timestamp="1432047636">16</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Henrichs, J</author><author>Bongers-Schokking, J J</author><author>Schenk, J J</author><author>Ghassabian, A</author><author>Schmidt, H G</author><author>Visser, T J</author><author>Hooijkaas, H</author><author>de Muinck Keizer-Schrama, S M P F</author><author>Hofman, A</author><author>Jaddo, V V W</author><author>Visser, W</author><author>Steegers, E A P</author><author>Verhulst, F C</author><author>de Rijke, Y B</author><author>Tiemeier, H</author></authors></contributors><titles><title>Maternal thyroid function during early pregnancy and cognitive functioning in early childhood: the Generation R Study</title><secondary-title>Journal of Clinical Endocrinology and Metabolism</secondary-title></titles><periodical><full-title>Journal of Clinical Endocrinology and Metabolism</full-title></periodical><pages>4227-4234</pages><volume>95</volume><number>9</number><section>4227</section><dates><year>2010</year></dates><urls></urls><electronic-resource-num>10.1210/jc.2010-0415</electronic-resource-num></record></Cite></EndNote>] found exposure to maternal hypothyroxinemia *in utero* to be associated with an increased odds of expressive language and nonverbal cognitive delays when compared to non-exposed offspring. Oostenbroek et al. (2017) found greater odds of hyperactivity/inattention (as reported by teachers; at the hypothyroxinemic cut point of the 5th percentile) and emotional problems (as reported by parents; at the hypothyroxinemic cut point of the 10th percentile) in offspring born to hypothyroxinemic mothers compared to mothers with normal thyroid hormone levels. Additionally, Gyllenberg et al. [ADDIN EN.CITE ADDIN EN.CITE.DATA] found a statistically significant association between exposure to maternal hypothyroxinemia and odds of being diagnosed with schizophrenia, while Román et al. [ADDIN EN.CITE <EndNote><Cite ExcludeAuth="1"><Author>Román</Author><Year>2013</Year><RecNum>26</RecNum><DisplayText>(2013)</DisplayText><record><rec-number>26</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1432047642">26</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Román, G C</author><author>Ghassabian, A</author><author>Bongers-Schokking, J</author><author>Jaddoe, V W V</author><author>Hofman, A </author><author>de Rijke, Y B</author><author>Verhulst, F C</author><author>Tiemeier, H</author></authors></contributors><titles><title>Association of gestational maternal hypothyroxinemia and increased autism risk</title><secondary-title>Annals of Neurology</secondary-title></titles><periodical><full-title>Annals of Neurology</full-title></periodical><pages>733-742</pages><volume>74</volume><number>5</number><section>733</section><dates><year>2013</year></dates><urls></urls><electronic-resource-num>10.1002/ana.23976</electronic-resource-num></record></Cite></EndNote>] found that maternal hypothyroxinemia was associated with increased odds of having a probable autistic child. Further, Modesto et al. [ADDIN EN.CITE ADDIN EN.CITE.DATA] found a relationship between ADHD and severe maternal hypothyroxinemia.

This section presents an alternative population-based approach that estimates the shift in the population of hypothyroxinemic, pregnant women for a specific gestational week that would result from perchlorate exposure. Specifically, an approach is outlined by which the baseline fT4 distribution for the median iodine intake from the BBDR model is evaluated to determine the hypothyroxinemic cut point based on this distribution. In this report, the EPA assumes that hypothyroxinemia occurs at the 10th percentile fT4 level. Then, by evaluating predicted fT4 distributions for the 75 µg/day of iodide (low-iodine intake) population with various perchlorate doses, the increase in the proportion of the population below the hypothyroxinemic cut point is determined. This approach is presented visually in [REF _Ref488672040 \h].

Figure [SEQ Figure * ARABIC]. Outline of Approach to Determine the Proportion of Pregnant Mothers Who Are Below a Hypothyroxinemic Cut Point Due to Perchlorate

[EMBED Visio.Drawing.15]

7.1 Evaluation of the Shift of Early Pregnancy Mothers into the Hypothyroxinemic Range

Given that the majority of studies presented in [REF _Ref482284683 \h] measured fT4 levels in early pregnancy around 12, 13, or 16 GW, these are the weeks concentrated on for this analysis as well.

To evaluate how the proportion of women with hypothyroxinemia changes based on perchlorate, it is necessary to evaluate the fT4 distributions derived in Section [REF _Ref482392642 \r \h]. Specifically, once the fT4 distribution for the median iodine intake population at each gestational week is estimated (as presented in [REF _Ref512860801 \h] through [REF _Ref512860816 \h]), it is possible to determine the definition of hypothyroxinemia for each gestational week. That is, defining hypothyroxinemia as the 10th percentile of the median-iodine intake population, a cut point for hypothyroxinemia, can be set for each gestational week. The EPA opted to perform this analysis using output from the BBDR model that was calibrated to represent the median person in the population, as opposed to the analyses in Section [REF _Ref456208917 \r \h], which used BBDR model output that was calibrated to represent a potentially sensitive person in the population. These "median" BBDR results are more appropriate for this analysis of the shift in the hypothyroxinemic population given that the analysis is based on the full distribution of fT4 levels and the approach aims to avoid the precursor effect to neurodevelopment (i.e., hypothyroxinemia).

Based on this hypothyroxinemic cut point, the proportion of people in the low-iodine intake population who would be considered hypothyroxinemic before any exposure to perchlorate was then assessed. This was done by evaluating the entire distribution of fT4 for the low-iodine population to identify the percentile that aligns with the median-iodine hypothyroxinemic cut point fT4 concentration presented in column 1 of [REF _Ref482965369 \h]. This percentile, which represents the proportion of individuals in the low-iodine group who are considered hypothyroxinemic before any perchlorate exposure, is presented in column 2 of [REF _Ref482965369 \h]. It is now possible to isolate the impact of perchlorate on the low-iodine population with respect to the resulting increase in the proportion of individuals with hypothyroxinemia. Based on the proportion of individuals identified in column 2 of [REF _Ref482965369 \h], it is now possible to evaluate the full distributions of fT4 for given doses of perchlorate to determine when there is a 1% or 5% increase in the proportion of individuals with hypothyroxinemia. The results of this analysis are presented in columns 3 and 4, respectively, of [REF _Ref482965369 \h].

Table [SEQ Table * ARABIC]. Summary of Results for the Amount of Perchlorate Needed to Increase the Proportion of Low-Iodine Intake, Hypothyroxinemic Individuals by a Defined Percentage (with hypothyroxinemia defined as fT4< 10th Percentile)

Gestational Week	fT4 (pmol/L) at the Hypothyroxinemic Cut Point (i.e.,10th Percentile of 170 µg/day Iodine Intake Group) (Column 1)	Corresponding Percentile in 75 µg/day Iodine Intake Group (Column 2)	Perchlorate Dose (µg/kg/day) Associated with a 1% Increase in Proportion Hypothyroxinemic (Column 3)	Perchlorate Dose (µg/kg/day) Associated with a 5% Increase in Proportion Hypothyroxinemic (Column 4)
12	8.09	32.4	1.0	5.8

13	8.07	32.2	1.1	5.9
[a] pTSH in BBDR model set to 1.				

7.2 Uncertainties in the Results Pertaining to Evaluating the Proportion of Individuals Below a Hypothyroxinemic Cut Point

In determining the proportion of a population that would be considered hypothyroxinemic there are several uncertainties. For example, there is uncertainty with respect to determining the appropriate effect size to constitute an "adverse" effect or at least an effect that may have some biological consequence. For a continuous parameter with a defined baseline distribution, a cut point at the tail of the distribution (e.g., 5th or 10th percentile) is often used to distinguish between within and outside the reference or "normal" range. The idea is that it is desirable to have individuals within the reference range because those at the extreme of the distribution may already have or be more susceptible to developing clinical disease. The 10th percentile cut point was used to define hypothyroxinemia and is not based upon a specific clinical endpoint (e.g., goiter). The exact cut point does not affect this analysis significantly if the measure of effect is the shift in the tail end of fT4 and its relationship with neurodevelopment or the shift in the tail (cut point) of the distribution. This can be seen in [REF _Ref486235305 \h] and [REF _Ref486235314 \h], which demonstrate an analogous analysis, but using the 2.5th or 5th percentile as the defined cut point for hypothyroxinemia, respectively. These tables demonstrate the dose of perchlorate associated with a 1% increase in the proportion of individuals who would be considered hypothyroxinemic ranges from 1.0 µg/kg/day to 2.2 µg/kg/day, depending on the cut point used and gestational week of interest. Additionally, the results range from 5.8 to 11.5 µg/kg/day when evaluating the dose of perchlorate associated with a 5% increase in the proportion of individuals who are hypothyroxinemic, depending on the cut point used and gestational week of interest.

Further, intra-individual variance in fT4 may also be a factor affecting the tail of the distribution, as about 10% of the population variance is made up of intra-individual variance (Andersen et al., 2002). Thus, a single fT4 measurement may represent hypothyroxinemia for one individual at a certain time point, but not for the same individual at a different time point or for another individual.

Table [SEQ Table * ARABIC]. Summary of Results for the Amount of Perchlorate Needed to Increase the Proportion of Low-Iodine Intake, Hypothyroxinemic Individuals by a Defined Percentage: Hypothyroxinemic Cut Point at 2.5th Percentile fT4 of 170 µg/day Iodine Intake Group

Gestational Week	fT4 (pmol/L) at the Hypothyroxinemic Cut Point (i.e., 2.5th Percentile of 170 µg/day Iodine Intake Group)	Corresponding Percentile in 75 *µg/day* Iodine Intake Group	Perchlorate Dose (µg/kg/day) Associated with a 1% Increase in Proportion Hypothyroxinemic	Perchlorate Dose (µg/kg/day) Associated with a 5% Increase in Proportion Hypothyroxinemic
12	6.72	10.1	2.2	11.3
13	6.70	10.0	2.2	11.5

Table [SEQ Table * ARABIC]. Summary of Results for the Amount of Perchlorate Needed to Increase the Proportion of Low-Iodine Intake, Hypothyroxinemic Individuals by a Defined Percentage: Hypothyroxinemic Cut Point at 5th Percentile fT4 of 170 µg/day Iodine Intake Group

Gestational Week	fT4 (pmol/L) at the Hypothyroxinemic Cut Point (i.e., 5th Percentile of 170 µg/day Iodine Intake Group)	Corresponding Percentile in 75 µg/day Iodine Intake Group	Perchlorate Dose (µg/kg/day) Associated with a 1% Increase in Proportion Hypothyroxinemic	Perchlorate Dose (µg/kg/day) Associated with a 5% Increase in Proportion Hypothyroxinemic
12	7.36	18.6	1.5	7.7
13	7.33	18.3	1.5	7.8

8. Other Health Effects Potentially Associated with Perchlorate

The competitive inhibition of the thyroidal NIS by perchlorate largely results in health effects associated with hypothyroxinemia or hypothyroidism. Perchlorate has the potential to affect other organ systems that contain NISs, such as the salivary glands, gastric mucosa, ovaries, lactating breast tissue, and placenta [ADDIN EN.CITE <EndNote><Cite><Author>Portulano</Author><Year>2014</Year><RecNum>218</RecNum><DisplayText>(Portulano, Paroder-Belenitsky, & Carrasco, 2014)</DisplayText><record><rec-number>218</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468245499">218</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Portulano, C. </author><author>Paroder-Belenitsky, M.</author><author>Carrasco, N.</author></authors></contributors><titles><title>The Na+/I- symporter: Mechanism and medical impact</title><secondary-title>Endocrine Reviews</secondary-title></titles><periodical><full-title>Endocrine Reviews</full-title></periodical><pages>106-149</pages><volume>35</volume><number>1</number><dates><year>2014</year></dates><urls></urls></record></Cite></EndNote>], though few studies have linked perchlorate to effects on these organ systems. Perchlorate may also cause oxidative stress [ADDIN EN.CITE <EndNote><Cite><Author>Schreinemachers</Author><Year>2015</Year><RecNum>219</RecNum><DisplayText>(Schreinemachers, Ghio, Sobus, & Williams, 2015; Zhao, Zhou, Chen, Li, & Ding, 2015)</DisplayText><record><rec-number>219</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468245554">219</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Schreinemachers, D.M.</author><author>Ghio, A.J.</author><author>Sobus, J.R.</author><author>Williams, M.A.</author></authors></contributors><titles><title>Perchlorate exposure is associated with oxidative stress and indicators of serum iron homeostasis among NHANES 2005-2008 subjects</title><secondary-title>Biomarker Insights</secondary-title></titles><periodical><full-title>Biomarker Insights</full-title></periodical><pages>9-19</pages><volume>10</volume><dates><year>2015</year></dates><urls></urls></record></Cite><Cite><Author>Zhao</Author><Year>2015</Year><RecNum>221</RecNum><record><rec-number>221</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468245660">221</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Zhao, X.</author><author>Zhou, P.</author><author>Chen, X.</author><author>Li, X.</author><author>Ding, L.</author></authors></contributors><titles><title>Perchlorate-induced oxidative stress in isolated liver mitochondria</title><secondary-title>Ecotoxicology</secondary-title></titles><periodical><full-title>Ecotoxicology</full-title></periodical><pages>1846-53</pages><volume>23</volume><number>10</number><dates><year>2015</year></dates><urls></urls></record></Cite></EndNote>]. The body contains a number of antioxidant defenses that act to attenuate this damage, but chronic low-dose exposure to environmental toxicants could have a range of adverse outcomes [ADDIN EN.CITE <EndNote><Cite><Author>Tyrrell</Author><Year>2013</Year><RecNum>220</RecNum><DisplayText>(Tyrrell, Melzer, Henley, Galloway, & Osborne, 2013)</DisplayText><record><rec-number>220</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468245598">220</key></foreign-

keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Tyrrell, J.</author><author>Melzer, D.</author><author>Henley, W.</author><author>Galloway, T.S.</author><author>Osborne, N.J.</author></authors></contributors><titles><title>Associations between socioeconomic status and environmental toxicant concentrations in adults in the USA: NHANES 2001-2010</title><secondary-title>Environment International</secondary-title></titles><periodical><full-title>Environment International</full-title></periodical><pages>328-35</pages><volume>59</volume><dates><year>2013</year></dates><urls></urls></record></Cite></EndNote>], some of which cannot be immediately predicted from the recognized mode of action. Currently, there is limited evidence to implicate chronic low-dose exposure to perchlorate in causing disease states other than hypothyroxinemia and hypothyroidism; however, evidence does suggest the need for further studies to determine processes other than competitive inhibition of the NIS that may occur (ATSDR, 2008).

This section provides a brief overview of the potential adverse health effects that could be related to perchlorate, given what is known regarding its mode of action. These health effects are not captured in the analysis of approaches for potentially informing the derivation of a perchlorate MCLG. This information provides context for the limited data on the full potential adverse health effects of perchlorate. The information presented here supports the idea that protecting against the shift into a hypothyroxinemic state, or the subsequent adverse neurologic impacts resulting from that shift in fT4, may also protect against other adverse health effects of which the EPA is not yet fully aware.

8.1 Hypothyroidism

Endocrine systems are to some extent capable of adapting to environmental stressors. The negative feedback loop that drives the HPT axis is highly nuanced, and the easiest components to measure are circulating levels of T4, T3, and TSH. The system is also capable of self-regulating other components that are harder to measure, including altering receptor numbers; upregulating deiodinases; and changing plasma concentrations of carrier proteins such as TBG, TTR, and albumin [ADDIN EN.CITE <EndNote><Cite><Author>Zoeller</Author><Year>2007</Year><RecNum>186</RecNum><DisplayText>(Zoeller et al., 2007)</DisplayText><record><rec-number>186</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1466202457">186</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Zoeller, R Thomas</author><author>Tan, Shirlee W</author><author>Tyl, Rochelle W</author></authors></contributors><titles><title>General background on the hypothalamic-pituitary-thyroid (HPT) axis</title><secondary-title>Critical Reviews in Toxicology</secondary-title></titles><periodical><full-title>Critical reviews in toxicology</full-title></periodical><pages>11-53</pages><volume>37</volume><number>1-2</number><dates><year>2007</year></dates><isbn>1040-8444</isbn><urls></urls></record></Cite></EndNote>]. This type of compensatory mechanism has been observed in human perchlorate dosing studies [ADDIN EN.CITE ADDIN EN.CITE.DATA]. There were no measurable changes in TSH, T3, or T4 despite reduced uptake of iodide in the 2-week studies [ADDIN EN.CITE <EndNote><Cite><Author>Lawrence</Author><Year>2000</Year><RecNum>228</RecNum><DisplayText>(Greer et al., 2002; Lawrence et al., 2000)</DisplayText><record><rec-number>228</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468246590">228</key></foreign-

keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Lawrence, J.E.</author><author>S.H. Lamm</author><author>S. Pino</author><author>K. Richman</author><author>Braverman, L</author></authors></contributors><titles><title>The effect of short-term low-dose perchlorate on various aspects of thyroid function</title><secondary-title>Thyroid</secondary-title></titles><periodical><full-title>Thyroid</full-title></periodical><pages>659-663</pages><volume>10</volume><number>8</number><dates><year>2000</year></dates><urls></urls></record></Cite><Cite><Author>Greer</Author><Year>2002</Year><RecNum>204</RecNum><record><rec-number>204</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1467812686">204</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Greer, Monte A</author><author>Goodman, Gay</author><author>Pleus, Richard C</author><author>Greer, Susan E</author></authors></contributors><titles><title>Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans</title><secondary-title>Environmental Health Perspectives</secondary-title></titles><periodical><full-title>Environmental Health Perspectives</full-title></periodical><pages>927</pages><volume>110</volume><number>9</number><dates><year>2002</year></dates><urls></urls></record></Cite></EndNote>]. It must be noted that, because the adult euthyroid human thyroid contains several months of T4 stored in the colloid, it is not expected that a 2-week study would result in a change in thyroid status (Dunn & Dunn, 2000, and Brabant et al., 1992, both as cited in Greer et al., 2002). On the contrary, in a study with chronic low-dose perchlorate exposure for 6 months, the authors suggested continued compensation for reduced iodide uptake because there were no changes in radiolabeled iodide uptake or thyroid hormone measurements [ADDIN EN.CITE <EndNote><Cite><Author>Braverman</Author><Year>2006</Year><RecNum>225</RecNum><DisplayText>(L Braverman et al., 2006)</DisplayText><record><rec-number>225</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468246163">225</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Braverman, L</author><author>Pearce, E.N.</author><author>He, X.</author><author>Pino, S.</author><author>Seeley, M.</author><author>Beck, B.</author><author>Magnani, B.</author><author>Bleunt, B.C.</author><author>Firek, A.</author></authors></contributors><titles><title>Effects of six months of daily low-dose perchlorate exposure on thyroid function in healthy volunteers</title><secondary-title>Journal of Clinical Endocrinology and Metabolism</secondary-title></titles><periodical><full-title>Journal of Clinical Endocrinology and Metabolism</full-title></periodical><pages>2721-94</pages><volume>91</volume><number>7</number><dates><year>2006</year></dates><urls></urls></record></Cite></EndNote>]. However, the sample size for the Braverman et al. study was low (n = 13; double-blind, randomized trial). Also, urinary iodide among participants in this study was considerably higher than the national average (mean 257.8 μg/total volume before 0.5 mg dose of perchlorate; mean 311.5 μg/total volume before 3 mg dose of perchlorate).

If there is a TSH-independent upregulation of NIS expression, it is unclear how long this can continue based on the available literature. However, it is apparent that at some point, the HPT axis is unable to adapt, and negative correlations between thyroid function and perchlorate begin to emerge [ADDIN EN.CITE ADDIN EN.CITE.DATA]. As stated by the EPA in the chemical assessment of perchlorate, "sustained changes in thyroid hormone and TSH secretion can result in thyroid hypertrophy and hyperplasia, possibly followed by hypothyroidism in people unable to compensate with an increase in thyroid iodide uptake" [ADDIN EN.CITE <EndNote><Cite><Author>U.S. EPA</Author><Year>2005</Year><RecNum>295</RecNum><Pages>14</Pages><DisplayText>(U.S. EPA, 2005, p. 14)</DisplayText><record><rec-number>295</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1470935048">295</key></foreign-keys><ref-type name="Government Document">46</ref-type><contributors><authors><author>U.S. EPA, </author></authors><secondary-authors><author>National Center for Environmental Assessment</author></secondary-authors></contributors><titles><title>Integrated Risk Information System chemical assessment summary: Perchlorate and perchlorate salts</title></titles><dates><year>2005</year></dates><urls><related-urls><url><style face="underline" font="default" size="100%">https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1007_summary.pdf</style><style face="normal" font="default" size="100%"> </style></url></related-urls></urls></record></Cite></EndNote>]. That is, given perchlorate's known mode of action, it is biologically plausible that perchlorate could be associated with hypothyroidism, especially in individuals without the ability to adequately respond to perchlorate's effect.

8.2 Cardiovascular Disease

Relatively small increases in TSH within the reference range have implications for cardiovascular health [ADDIN EN.CITE <EndNote><Cite><Author>Taylor</Author><Year>2013</Year><RecNum>259</RecNum><DisplayText>(Taylor, Razvi, Pearce, & Dayan, 2013)</DisplayText><record><rec-number>259</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468518896">259</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Taylor, P</author><author>Razvi, S.</author><author>Pearce, S. H.</author><author>Dayan, C. M.</author></authors></contributors><auth-address>Thyroid Research Group, Institute of Molecular Medicine, Cardiff University School of Medicine, Cardiff CF14 4XN, United Kingdom.</auth-address><titles><title>Clinical review: A review of the clinical consequences of variation in thyroid function within the reference range</title><secondary-title>Journal of Clinical Endocrinology and Metabolism</secondary-title></titles><periodical><full-title>Journal of Clinical Endocrinology and Metabolism</full-title></periodical><pages>3562-71</pages><volume>98</volume><number>9</number><edition>2013/07/05</edition><keywords><keyword>Cardiovascular Diseases/blood/physiopathology</keyword><keyword>Female</keyword><keyword>Humans</keyword><keyword>Male</keyword><keyword>Pregnancy</keyword><keyword>Pregnancy Outcome</keyword><keyword>Reference Values</keyword><keyword>Risk Factors</keyword><keyword>Thyroid Diseases/ blood/physiopathology</keyword><keyword>Thyroid Gland/ physiopathology</keyword><keyword>Thyroid Hormones/ blood</keyword></keywords><dates><year>2013</year><pub-dates><date>Sep</date></pub-dates></dates><isbn>1945-7197 (Electronic)
0021-972X (Linking)</isbn><accession-num>23824418</accession-num><urls></urls><electronic-resource-num>10.1210/jc.2013-1315</electronic-resource-num><remote-database-provider>NLM</remote-database-

provider><language>eng</language></record></Cite></EndNote>]. Biomarkers such as total serum cholesterol, low-density lipoprotein (LDL) cholesterol level, and triglycerides have been shown to increase in response to increases in TSH [ADDIN EN.CITE <EndNote><Cite><Author>Asvold</Author><Year>2007</Year><RecNum>223</RecNum><DisplayText>(Asvold, Vatten, Nilsen, & Bjoro, 2007; Canaris, Manowitz, Mayor, & Ridgway, 2000)</DisplayText><record><rec-number>223</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468245905">223</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Asvold, B.</author><author>Vatten, L. J.</author><author>Nilsen, T.</author><author>Bjoro, T. </author></authors></contributors><titles><title>The association between TSH within the reference range and serum lipid concentrations in a population-based study. The HUNT study</title><secondary-title>European Journal of Endocrinology</secondary-title></titles><periodical><full-title>European Journal of Endocrinology</full-title></periodical><pages>181-6</pages><volume>156</volume><dates><year>2007</year></dates><urls></urls></record></Cite><Cite><Author>Canaris</Author><Year>2000</Year><RecNum>226</RecNum><record><rec-number>226</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468246348">226</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Canaris, G. J.</author><author>Manowitz, N. R.</author><author>Mayor, G.</author><author>Ridgway, E. C.</author></authors></contributors><titles><title>The Colorado Thyroid Disease Prevalence Study</title><secondary-title>Archives of Internal Medicine</secondary-title></titles><periodical><full-title>Archives of Internal Medicine</full-title></periodical><pages>526-534</pages><volume>160</volume><dates><year>2000</year></dates><urls></urls></record></Cite></EndNote>]. Additionally, changes in thyroid hormones can damage the heart and vasculature [ADDIN EN.CITE <EndNote><Cite><Author>Suh</Author><Year>2015</Year><RecNum>231</RecNum><DisplayText>(Suh & Kim, 2015)</DisplayText><record><rec-number>231</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468246779">231</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Suh, S.</author><author>Kim, D.K.</author></authors></contributors><titles><title>Subclinical hypothyroidism and cardiovascular disease</title><secondary-title>Endocrinology and Metabolism</secondary-title></titles><periodical><full-title>Endocrinology and Metabolism</full-title></periodical><pages>246-251</pages><volume>30</volume><dates><year>2015</year></dates><urls></urls></record></Cite></EndNote>]. Even subclinical hypothyroidism could impair ventricular relaxation and filling, decrease exercise tolerance, affect cardiomyocyte function, and affect vascular smooth muscle [ADDIN EN.CITE ADDIN EN.CITE.DATA]. Competitive binding of perchlorate to the thyroidal NIS can cause increases in circulating TSH. If chronic perchlorate exposure occurs, TSH may become elevated for sufficient durations to alter circulating lipids and affect cardiac function.

9. Conclusion

This report describes a proposed methodology that follows the SAB recommendation to inform development of an MCLG for perchlorate [ADDIN EN.CITE <EndNote><Cite><Author>SAB</Author><Year>2013</Year><RecNum>50</RecNum><DisplayText>(SAB, 2013)</DisplayText><record><rec-number>50</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1437138201">50</key></foreign-keys><ref-type name="Government Document">46</ref-type><contributors><authors><author>SAB,</author></authors><secondary-authors><author>U.S. Environmental Protection Agency,</author></secondary-authors></contributors><titles><title>Advice on approaches to derive a maximum contaminant level goal for perchlorate. EPA-SAB-13-004</title></titles><dates><year>2013</year></dates><pub-location>Washington, DC</pub-location><urls></urls></record></Cite></EndNote>]. The methodology assesses perchlorate exposure by examining predicted impacts on maternal fT4 levels in pregnant women prior to mid-gestation and subsequent adverse neurodevelopmental impacts in their offspring. Additionally, an approach is presented that does not directly quantify neurodevelopmental impacts but evaluates a shift in fT4 into a hypothyroxinemic state, which may increase the risk of neurodevelopmental impacts. All of the approaches evaluate effects at low iodine intakes, considering a distribution of fT4 level. This is opposed to the more common approach of exploring the effect of a contaminant on a mean individual from a sensitive life stage. In taking this distributional approach, the EPA is able to isolate and explore the impact of perchlorate on a more sensitive group of individuals. This decreases but does not eliminate the uncertainty associated with ensuring that an MCLG protects the most sensitive population with a margin of safety.

To develop the proposed methodology for informing the derivation of an MCLG, the EPA conducted a literature review to identify studies that could connect the output of the BBDR model to neurodevelopmental effects. In reviewing this literature, the EPA identified five studies from which a further analysis could be done to evaluate incremental changes in fT4 and associated neurodevelopmental changes. Additionally, the majority of studies identified support the notion that avoiding a shift in the proportion of the population at risk of hypothyroxinemia may avoid adverse neurodevelopmental outcomes (see Section [REF _Ref482275380 \n \h]).

Using the BBDR model and the five studies identified, the EPA prepared an analysis that characterize how much neurodevelopmental outcomes are expected to change given decreased iodine intake and increased perchlorate exposure. The Pop et al. (1999, 2003) relationships for PDI may be the most sensitive in regard to the change predicted in the neurodevelopmental outcome. This may be due to the fact that this analysis applies specifically to the hypothyroxinemic population. Endendijk et al. (2017) shows the least change in regard to the change in anxiety/depression score for the doses of perchlorate evaluated.

Results from the analyses of Section [REF _Ref456208917 \n \h] are summarized in [REF _Ref491157076 \h] and [REF _Ref512619253 \h]. Additional results for other doses of perchlorate, impact using the lower 95% confidence interval, and additional fT4 percentiles are presented in Section [REF _Ref456208917 \n \h].

Table [SEQ Table * ARABIC]. Summary of Estimated Changes in Neurodevelopmental Outcomes Based on Central Beta Estimates due to a Change in Perchlorate Dose from 0 µg/kg/day at the 50th Percentile of fT4

Dose of Perchlorate (µg/kg/day)	Gestational Week 12					Gestational Week 13			
	fT4 (pmol/L)	Pop et al. (1999) ΔPDI[a]	Pop et al. (2003) ΔPDI[a]	Pop et al. (2003) ΔMDI[a]	Endendijk et al. (2017) ΔAD[a]	fT4 (pmol/L)	Finken et al. (2013) ΔRTSD[a]	Korevaar et al. (2016) ΔIQ[a] Quadratic	Korevaar et al. (2016) ΔIQ[a] EPA Independent Analysis
Iodine Intake = 170 µg/day									
0	10.67	N/A	N/A	N/A	N/A	10.64	N/A	N/A	N/A
Iodine Intake = 75 µg/day									
0	8.85	N/A	N/A	N/A	N/A	8.84	N/A	N/A	N/A
1	8.78	-0.60	-0.60	-0.45	0.01	8.77	0.34	-0.05	-0.14
10	8.27	-4.94	-4.88	-3.66	0.07	8.27	2.83	-0.48	-1.16

[a] Result based on central, lower and upper 95% CI effect estimates; BBDR model output using pTSH = 0.398; calibrated for median population. Additional details can be found in Appendix A.

Table [SEQ Table * ARABIC]. Summary of Estimated Changes in Neurodevelopmental Outcomes Based on Upper Beta Estimates due to a Change in Perchlorate Dose from 0 μg/kg/day at the 50th Percentile of fT4

Dose of Perchlorate (μg/kg/day)	Gestational Week 12					Gestational Week 13			
	fT4 (pmol/L)	Pop et al. (1999) ΔPDI[a]	Pop et al. (2003) ΔPDI[a]	Pop et al. (2003) ΔMDI[a]	Endendijk et al. (2017) ΔAD[a]	fT4 (pmol/L)	Finken et al. (2013) ΔRTSD[a]	Korevaar et al. (2016) ΔIQ[a] Quadratic	Korevaar et al. (2016) ΔIQ[a] EPA Independent Analysis
Iodine Intake = 170 μg/day									
0	10.67	N/A	N/A	N/A	N/A	10.64	N/A	N/A	N/A
Iodine Intake = 75 μg/day									
0	8.85	N/A	N/A	N/A	N/A	8.84	N/A	N/A	N/A
1	8.78	-1.21	-0.91	-0.75	0.01	8.77	0.66	-0.39	-0.24
10	8.27	-9.88	-7.44	-6.16	0.07	8.27	5.48	-3.35	-2.07

[a] Result based on central, lower and upper 95% CI effect estimates; BBDR model output using pTSH = 0.398; calibrated for median population. Additional details can be found in Appendix A.

Results in [REF _Ref492395898 \h] and [REF _Ref512619294 \h] present the dose of perchlorate associated with a unit change in the endpoint specific to the study of interest using the central and upper betas, respectively. These results provide a different perspective on how to evaluate the potential impacts of perchlorate on maternal fT4 (as predicted by the BBDR model) and subsequent neurodevelopmental impacts (as predicted by the epidemiologic literature). The same approach was used to estimate these doses as was described in Section [REF _Ref456208917 \n \h].

Table [SEQ Table * ARABIC]. Predicted Dose of Perchlorate per Unit Change in Neurodevelopmental Measure for Low-Iodine Intake Individuals Based on Central Effect Estimates at the Median fT4 level

Study	Endpoint	ΔfT4 in pmol/L (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 µg/day)	Dose of perchlorate per unit change in endpoint (µg/kg/day)[a]
Korevaar et al. (2016) Quadratic	IQ	-1.08 (12.2%)	23
Korevaar et al. (2016) EPA Independent Analysis	IQ	-0.47 (5.4%)	7.9
Pop et al. (2003)	MDI	-0.15 (1.7%)	2.2
Pop et al. (2003)	PDI	-0.12 (1.3%)	1.7
Pop et al. (1999)	PDI	-0.12 (1.3%)	1.7
Endendijk et al. (2017)	Anxiety / Depression Score	> -3.25 (> 36.7%)	> 150
Finken et al. (2013)	SD of Reaction Time	-0.21 (2.4%)	3.0
N/A	1% or 5% increase in proportion of hypothyroxinemic pregnant women[b]	N/A	1.0–1.1[c] [1%] 5.8–5.9[c] [5%]

[a] Based on the regression analysis for the range of fT4 data within each study. Central beta estimates of the low-iodine intake population (= 75 µg/day) are presented.
[b] Hypothyroxinemia defined as fT4 < 10th percentile.
[c] Range based on gestational week used to perform the analysis (12 to 13 weeks).

Table [SEQ Table * ARABIC]. Predicted Dose of Perchlorate per Unit Change in Neurodevelopmental Measure for Low-Iodine Intake Individuals Based on Upper Effect Estimates at the Median fT4 level

Study	Endpoint	ΔfT4 in pmol/L (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 µg/day)	Dose of perchlorate per unit change in endpoint (µg/kg/day)[a]
Korevaar et al. (2016) Quadratic	IQ	-0.17 (1.9%)	2.5
Korevaar et al. (2016) EPA Independent Analysis	IQ	-0.28 (3.1%)	4.2
Pop et al. (2003)	MDI	-0.09 (1.0%)	1.3
Pop et al. (2003)	PDI	-0.08 (0.9%)	1.1
Pop et al. (1999)	PDI	-0.06 (0.6%)	0.8
Endendijk et al. (2017)	Anxiety / Depression Score	> -3.25 (> 36.7%)	> 150
Finken et al. (2013)	SD of Reaction Time	-0.10 (1.2%)	1.5
N/A	1% or 5% increase in proportion of hypothyroxinemic pregnant women[b]	N/A	1.0–1.1[c] [1%] 5.8–5.9[c] [5%]

[a] Based on the regression analysis for the range of fT4 data within each study. Upper beta estimates of the low-iodine intake population (= 75 µg/day) are presented.
[b] Hypothyroxinemia defined as fT4 < 10^{th} percentile.
[c] Range based on gestational week used to perform the analysis (12 to 13 weeks).

Results from the analysis informing the derivation of an MCLG based on the shift in the proportion of individuals with fT4 below a hypothyroxinemic cut point are presented in [REF _Ref482965957 \h] (recreated from [REF _Ref482965369 \h]).

Table [SEQ Table * ARABIC]. Summary of Results for the Amount of Perchlorate Needed to Increase the Proportion of Low-Iodine Intake, Hypothyroxinemic Individuals by a Defined Percentage (with hypothyroxinemia defined as fT4< 10^{th} Percentile)

Gestational Week	fT4 (pmol/L) at the Hypothyroxinemic Cut Point (i.e., 10^{th} Percentile of 170 µg/day Iodine Intake Group) (Column 1)	Corresponding Percentile in 75 µg/day Iodine Intake Group (Column 2)[a]	Perchlorate Dose (µg/kg/day) Associated with a 1% Increase in Proportion Hypothyroxinemic (Column 3)[a]	Perchlorate Dose (µg/kg/day) Associated with a 5% Increase in Proportion Hypothyroxinemic (Column 4)[a]
12	8.09	32.4	1.0	5.8
13	8.07	32.2	1.1	5.9

[a]pTSH in BBDR model set to 1.

10. References

[ADDIN EN.REFLIST]

Message

From: Forsgren, Lee [Forsgren.Lee@epa.gov]
Sent: 1/8/2020 4:23:53 PM
To: Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]
CC: Aguirre, Janita [Aguirre.Janita@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Nagle, Deborah [Nagle.Deborah@epa.gov]; Behl, Betsy [Behl.Betsy@epa.gov]; Wendelowski, Karyn [wendelowski.karyn@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]
Subject: RE: revised perchlorate briefing
Attachments: Option Selection for Perchlorate 1-9-20v2.cb.docx

Jennifer here are my relatively minor edits incorporated into the edits Charlotte made.

From: Mclain, Jennifer <Mclain.Jennifer@epa.gov>
Sent: Wednesday, January 8, 2020 10:55 AM
To: Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Forsgren, Lee <Forsgren.Lee@epa.gov>
Cc: Aguirre, Janita <Aguirre.Janita@epa.gov>; Mejias, Melissa <mejias.melissa@epa.gov>; Tiago, Joseph <Tiago.Joseph@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Nagle, Deborah <Nagle.Deborah@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Wendelowski, Karyn <wendelowski.karyn@epa.gov>; Tovar, Katlyn <tovar.katlyn@epa.gov>
Subject: RE: revised perchlorate briefing

Thank you Charlotte for the quick response! We will turn this around quickly.
Lee – let us know if you have any additional comments.

Jennifer

From: Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Sent: Wednesday, January 8, 2020 10:09 AM
To: Mclain, Jennifer <Mclain.Jennifer@epa.gov>
Cc: Aguirre, Janita <Aguirre.Janita@epa.gov>; Mejias, Melissa <mejias.melissa@epa.gov>; Tiago, Joseph <Tiago.Joseph@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Nagle, Deborah <Nagle.Deborah@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Wendelowski, Karyn <wendelowski.karyn@epa.gov>; Forsgren, Lee <Forsgren.Lee@epa.gov>; Tovar, Katlyn <tovar.katlyn@epa.gov>
Subject: RE: revised perchlorate briefing

Thanks! I made a few tweaks in areas that I highlighted in green. Let me know if you are ok with those suggested changes. Looks good.
Cc'ing Lee for his input too.

From: Mclain, Jennifer <Mclain.Jennifer@epa.gov>
Sent: Tuesday, January 07, 2020 5:51 PM
To: Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Aguirre, Janita <Aguirre.Janita@epa.gov>; Mejias, Melissa <mejias.melissa@epa.gov>; Tiago, Joseph <Tiago.Joseph@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Nagle, Deborah <Nagle.Deborah@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Wendelowski, Karyn <wendelowski.karyn@epa.gov>
Subject: revised perchlorate briefing

Charlotte
Attached is a revised perchlorate briefing document per our meeting with Dave this morning. I've also attached the track changes version so you can see the specifics of where we made changes.
Please let us know if you have any questions.
Jennifer

Jennifer L. McLain, Director
Office of Ground Water and Drinking Water
U.S. EPA

Message

From:	McLain, Jennifer L. [McLain.Jennifer@epa.gov]
Sent:	5/18/2020 7:00:39 PM
To:	Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]
CC:	Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Braschayko, Kelley [braschayko.kelley@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]
Subject:	FW: Notice of Final Action on Perchlorate
Attachments:	Draft Perchlorate Final Action FRN 5-18-20 v1 Redline.docx; Draft Perchlorate Final Action FRN 5-18-20 v1 Clean.docx; Perchlorate Action Memo 5-18-20.docx

Charlotte – as agreed, I'm sending you the draft final perchlorate FRN for review. The redline includes the changes made since the FAR. I'm also including the draft Action Memo. Please let us know if your preference is to have these submitted to OW through CMS now or after you have reviewed. Let me know if you want to talk.

Jennifer

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Monday, May 18, 2020 2:48 PM
To: McLain, Jennifer L. <McLain.Jennifer@epa.gov>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Tiago, Joseph <Tiago.Joseph@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: FW: Notice of Final Action on Perchlorate

Jennifer:

Attached for transmission to OW are revised versions of the FRN for the Perchlorate Final Action. There is both a clean and track changes version that includes edits made since initiating FAR (including the edits you asked for on Saturday and adding 3 more SAB recommendations to page 14 that were in the proposal but were not included in the draft we provided you on Friday). Also please find clean version of the transmittal memo from you to Dave Ross and the Action memo incorporating your edits.

Please note that there is also a redline version of the Action Memo for you to see the responses to your comments on the document. I do not recommend transmitting that memo to OW.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Sent: Monday, May 18, 2020 2:18 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Notice of Final Action on Perchlorate

Hi Eric,

Attached are the revised Redline and Clean versions of the Perchlorate FR Notice. Once we are ready for OP's submittal to OMB let me know and I will provide a version that adheres to OP's file name formatting guidelines.

Thanks
Sam
==
Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Monday, May 18, 2020 1:14 PM
To: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Notice of Final Action on Perchlorate

Sam

1. Change the title please. This was requested by OGC at Sr. Leadership levels.
2. Provide the same level of detail on the SAB recommendations as was included in the proposal.
3. I don't think the HRRCA text is necessary and do not want to add it at this stage since there are OGC edits that already make this clear.

Eric

From: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Sent: Monday, May 18, 2020 12:41 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Notice of Final Action on Perchlorate

Hi Eric,

Here is a revised Redline of the document (from FAR). We had a few questions/issues for your consideration about the attached file. Specifically:,

1- Page #1, Notice Tittle: We did not accept the edits to the notice tittle. Because, the tittle of the notice was specifically crafted by OGC to capture the multiple actions EPA is taking. Suggest consulting with OGC before modifying this tittle.
2- Page #14, SAB Recommendations: SAB provided 4 main recommendations in 2013 but we only listed the first recommendation. Please advise if we should list all 4 recommendations here or not.
3- Page #26, Missing HRRCA Text: This language was offered by TAB in its 5-13-20 version of the draft FRN, but it did not show up in the version provided by OGWDW with Eric's & Jennifer's comments. We have inserted the language here for the reviewer's consideration. Please advise if we should keep it.

Once you provide your feedback, I will modify the redline version and also provide a Clean copy for transmittal.

Thanks
Sam
==
Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water

Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Monday, May 18, 2020 8:42 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Cc: McLain, Jennifer L. <McLain.Jennifer@epa.gov>; Tiago, Joseph <Tiago.Joseph@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
Subject: FW: Notice of Final Action on Perchlorate

Lisa and Sam
Attached are Jennifer's comments and edits on the draft FRN. I have responded to her questions in the attached and made some additional edits. Can you please get a revised clean version and another redline version that compares this document and the version that was distributed to FAR?
Thanks for your work on this.
Eric

From: McLain, Jennifer L. <McLain.Jennifer@epa.gov>
Sent: Saturday, May 16, 2020 11:39 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Notice of Final Action on Perchlorate

Looks very good. See p. 6 for my only concern w/the revisions.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, May 15, 2020 5:03 PM
To: McLain, Jennifer L. <McLain.Jennifer@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Tiago, Joseph <Tiago.Joseph@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
Subject: Notice of Final Action on Perchlorate

Jennifer

Attached for your approval and transmittal to the Office of Water for their approval and transmittal to the Office Policy for initiation of interagency review is a *Federal Register* notice titled: "Notice of Final Action on Perchlorate." Also attached for your review are a draft transmittal memo from you to the Assistant Administrator of Water, a draft Action Memorandum and a track changes version of the FR notice that denotes the changes made as a result of Final Agency Review.

On February 11, 2011, the EPA published a determination to regulate perchlorate in drinking water (76 FR 7762). On June 26, 2019 (84 FR 30524), the EPA published the proposed National Primary Drinking Water Regulation for Perchlorate and requested public comments on multiple alternative actions, including withdrawing the 2011 determination to regulate perchlorate. The EPA received approximately 1,500 comments on the proposed rule. In the attached notice, the EPA is withdrawing the 2011 Regulatory Determination and is making a final determination not to regulate perchlorate based on the Agency's consideration of public comments and the best available information.

I recommend that you approve and transmit the attached notice to the Office of Water for their review, approval and transmission to the Office of Policy to initiate interagency review in accordance with Executive Order 12866. If you need additional information or have questions pertaining to any aspect of this notice, please call me or have your staff contact Samuel Hernandez at 202-564-1735.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[EPA-HQ-OW-2018-0780, EPA–HQ–OW–2008–0692, EPA–HQ–OW– 2009–0297; FRL-XXXX-XX-OW]

RIN 2040-AF28

Drinking Water: Notice of Final Action on Perchlorate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of Regulatory Determination and Final Regulatory Determination.

SUMMARY: The Environmental Protection Agency (EPA) is announcing its withdrawal of the 2011 determination to regulate perchlorate in accordance with the Safe Drinking Water Act (SDWA). On February 11, 2011, the EPA published a *Federal Register* notice in which the Agency determined that perchlorate met the SDWA's criteria for regulating a contaminant. On June 26, 2019, the EPA published a proposed national primary drinking water regulation (NPDWR) for perchlorate and requested public comments on multiple alternative regulatory actions, including the alternative of withdrawing the 2011 regulatory determination for perchlorate. The EPA received approximately 1,500 comments on the proposed rule. The EPA has considered these public comments and based on the best available information the Agency is withdrawing the 2011 regulatory determination and is making a final determination to not regulate perchlorate. The EPA has determined that perchlorate does not occur with a frequency

and at levels of public health concern, and that regulation of perchlorate does not present a meaningful opportunity for health risk reduction for persons served by public water systems.

DATES: For purposes of judicial review, the regulatory determination in this document is issued as of *[insert date of publication in the* Federal Register*]*.

FOR FURTHER INFORMATION CONTACT: Samuel Hernandez, Office of Ground Water and Drinking Water, Standards and Risk Management Division (Mail Code 4607M), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone number: (202) 564-1735; email address: hernandez.samuel@epa.gov.

SUPPLEMENTARY INFORMATION: This notice is organized as follows:

I. General Information

A. Does This Action Apply to Me?

This action will not impose any requirements on anyone. Instead, this action notifies interested parties of the EPA's withdrawal of the 2011 regulatory determination for perchlorate and the final regulatory determination to not regulate perchlorate. This notice also provides a summary of the major comments received on the June 26, 2019 (84 FR 30524) proposed NPDWR for perchlorate.

B. How can I get Copies of this Document and other Related Information?

The EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2018–0780. Publicly available docket materials are available electronically at [HYPERLINK "http://www.regulations.gov/docket?D=EPA-HQ-OW-2018-0780"].

II. Background

A. What is Perchlorate?

Perchlorate is a negatively charged inorganic ion that is comprised of one chlorine atom bound to four oxygen atoms (ClO_4-), which is highly stable and mobile in the aqueous environment. Perchlorate comes from both natural and manmade sources. It is formed naturally via atmospheric processes and can be found within mineral deposits in certain geographical areas. It is also produced in the United States, and the most common compounds include ammonium perchlorate and potassium perchlorate used primarily as oxidizers in solid fuels to power rockets, missiles, and fireworks. Perchlorate can also result from the degradation of hypochlorite solutions used for water disinfection. The degradation into perchlorate occurs when hypochlorite solutions are improperly stored and handled. For the general population, most perchlorate exposure is through the ingestion of contaminated food or drinking water. At certain levels, perchlorate can prevent the thyroid gland from getting enough iodine, which can affect thyroid hormone production. For pregnant women with low iodine levels, sufficient changes in thyroid hormone levels may cause changes in the child's brain development. For infants, changes to thyroid hormone function can also impact brain development.

B. What is the purpose of this action?

The purpose of this action is to publish the EPA's notice to withdraw the 2011 regulatory determination and issue a final determination to not regulate perchlorate in drinking water. This notice presents the EPA's basis for this withdrawal and final regulatory determination, and the EPA's response to key issues raised by commenters in response to the June 26, 2019 (84 FR 30524) proposed rule (referred to hereinafter as "the 2019 proposal").

C. What is the EPA's statutory authority for this action?

The SDWA sets forth three criteria that must be met for the EPA to issue a maximum contaminant level goal (MCLG) and promulgate a national primary drinking water regulation (NPDWR). Specifically, the Administrator must determine that (1) "the contaminant may have an adverse effect on the health of persons"; (2) "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern"; and (3) "in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems" (SDWA 1412(b)(1)(A)).

The EPA has determined, based on data and analysis since the issuance of the 2011 regulatory determination, that perchlorate does not in fact meet the statutorily-prescribed criteria for regulation. As described in Sections III & VI of the 2019 proposal, the data and analysis in the record indicate that perchlorate does not occur in public water systems with a frequency and at levels of public health concern. Specifically, the peer-reviewed health effects analysis indicates that the concentration of perchlorate representing levels of public health concern (18-90 μg/L) is higher than the concentration considered in issuance of the 2011 regulatory determination (1-47 μg/L) (USEPA, 2019a). In addition, based on an evaluation of the nationally representative UCMR 1 systems, the updated occurrence analysis shows that the frequency of occurrence of perchlorate in public water systems at levels exceeding any of the alternative proposed MCLGs is significantly lower (0.38% - 0.02%) than the frequency considered in the analysis for the 2011 regulatory determination (4% - 0.39%) (USEPA, 2019b). The EPA estimates that, even at the most stringent regulatory level considered in the 2019 proposal (18 μg/L), not more than 15 systems (0.03% of all water systems in the U.S.) would need to take action to reduce levels of perchlorate. Based on this information, the EPA determines that perchlorate does not occur in public water systems "with a frequency…of public health concern" and thus does not meet the second criterion of the three required for regulation under the SDWA. In addition, while the third criterion is "in the sole judgement of the Administrator," the low occurrence provides ample support for the EPA's conclusion that the regulation of perchlorate does not present a "meaningful opportunity for health risk reduction for persons served by public water systems," within the meaning of 1412(b)(1)(A)(iii). Accordingly, because perchlorate no longer meets the statutory criteria for regulation, the EPA does not have the authority to issue a MCLG or promulgate a NPDWR for perchlorate.

The EPA's decision to withdraw the regulatory determination is supported by the legislative history underlying the 1996 amendments to the SDWA, which repealed the statutory requirement for the EPA to regulate an additional 25 contaminants every 3 years and replaced it with the current requirement for the EPA to determine whether regulation is warranted for five contaminants every five years. In describing the need for such amendment, the legislative history points to the view expressed at the Committee Hearing that "the current law is a one-size-fits-all program. It forces our water quality experts to spend scarce resources searching for dangers that often do not exist rather than identifying and removing real health risks from our drinking water" (S. Rep. 104-169 (1995) at 12). This amendment reflected Congress' clear intent that the EPA prioritize actual health risks in determining whether to regulate any particular contaminant. *See id* at 12 (noting that the amendment "repeals the requirement that the EPA regulate an additional 25 contaminants every 3 years replacing it with a new selection process that gives the EPA the discretion to identify contaminants that warrant regulation in the future").

The EPA's decision to withdraw the regulatory determination is also consistent with Congress' direction to prioritize the SDWA decisions based on the best available public health information. *See* 1412(b)(1)(B)(ii)(II) (findings supporting a determination to regulate "shall be based on the best available public health information"); 1412(b)(2)(A) (requiring that the EPA use "the best available, peer-reviewed science and supporting studies…" in carrying out any actions under this section). Although the EPA determined in 2011 that perchlorate met the criteria for regulation, new data and analysis developed by the Agency as part of the 2019 proposal demonstrate that the occurrence and health effects information used as the basis for the 2011 determination no longer constitute "best available information," are no longer accurate and no longer support the Agency's prioritization of perchlorate for regulation. Accordingly, not only is EPA not authorized to issue a MCLG or promulgate a NPDWR for perchlorate, but it would not be in the public interest to do so.

The EPA recognizes that the Act does not include a provision explicitly authorizing withdrawal of a regulatory determination. However, such authority is inherent in the authority to issue a regulatory determination under 1412(b)(1)(B)(ii)(II), particularly given the requirement that such determination be based on the "best available public health information," as discussed above. Accordingly, the EPA must have the inherent authority to withdraw a regulatory determination if the underlying information changes between regulatory determination and promulgation. In light of its concern that the EPA focus new contaminant regulations on priority health concerns, Congress could not have intended that the EPA's regulatory decision-making be hamstrung by older data when newer, more accurate scientific and public health data are available, especially when those data demonstrate that regulation of a new contaminant would not present a meaningful opportunity for health risk reduction.

Moreover, the EPA notes that the statute specifically provides that a decision to <u>not</u> regulate a contaminant is a final Agency action subject to judicial review. The SDWA, section 1412(b)(1)(B)(ii)(IV). Congress could have – but did not – specify the same with respect to determinations <u>to</u> regulate. Congress also did not explicitly prohibit the EPA from withdrawing or modifying a regulatory determination. Congress' silence with respect to determinations to regulate suggests that Congress intended that such a determination is not itself a final agency action, but rather, a preliminary step in a decision-making process culminating in a NPDWR and thus, subject to reconsideration based on new data and analysis considered during the 36 month promulgation process specified in the statute. Accordingly, reconsideration of this preliminary finding – and withdrawal of the determination based on subsequent analysis mandated for NPDWR development – is fully consistent with the statutory decision-making framework.

D. Statutory Framework and Perchlorate Regulatory History

Section 1412(b)(1)(B)(i) of the SDWA requires the EPA to publish every five years a Contaminant Candidate List (CCL). The CCL is a list of drinking water contaminants that are known or anticipated to occur in public water systems and are not currently subject to federal drinking water regulations. The EPA uses the CCL to identify priority contaminants for regulatory decision-making and information collection. Contaminants listed on the CCL may require future regulation under the SDWA. The EPA included perchlorate on the first, second, and third CCLs published in 1998 (63 FR 10274), 2005 (70 FR 9071), and 2009 (74 FR 51850).

The EPA collects data on the CCL contaminants to better understand their potential health effects and to determine the levels at which they occur in public water systems. The SDWA, section 1412(b)(1)(B)(ii) requires that, every five years, the EPA, after consideration of public comment, issue a determination of whether or not to regulate at least five contaminants on each CCL. For any contaminant that the EPA determines meets the SDWA criteria for regulation, under the SDWA, section 1412(b)(1)(E), the EPA must propose a NPDWR within two years and promulgate a final regulation within 18 months of the proposal (which may be extended by 9 additional months).

As part of its responsibilities under the SDWA, the EPA implements section 1445(a)(2), "Monitoring Program for Unregulated Contaminants." This section requires that once every five years, the EPA issue a list of no more than 30 unregulated contaminants to be monitored by public water systems. This monitoring is implemented through the Unregulated Contaminant Monitoring Rule (UCMR), which collects data from community water systems and non-transient, non-community water systems. The first four UCMRs collected data from a census of large water systems (serving more than 10,000 people) and from a statistically representative sample of small water systems. On September 17, 1999, the EPA published its first UCMR (64 FR 50556), which required all large systems and a representative sample of small systems to monitor for perchlorate and 25 other contaminants (USEPA, 1999). Water system monitoring data for perchlorate was collected from 2001 to 2005.

The EPA and other federal agencies asked the National Research Council (NRC) to evaluate the health implications of perchlorate ingestion. In its 2005 report, the NRC concluded that perchlorate exposure inhibits the transport of iodide[1] into the thyroid by a protein molecule

[1] For the purposes of this notice, "iodine" will be used to refer to dietary intake before entering the body. Once in the body, "iodide" will be used to refer to the ionic form.

known as the sodium/iodide symporter (NIS), which may lead to decreases in two thyroid hormones, thyroxine (T3) and triiodothyronine (T4), and increases in thyroid-stimulating hormone (TSH) [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a1mn5hjprkt","properties":{"formattedCitation":"(National Research Council (NRC), 2005b)","plainCitation":"(National Research Council (NRC), 2005b)","noteIndex":0},"citationItems":[{"id":350,"uris":["http://zotero.org/groups/945096/items/TN6HMC9D"],"uri":["http://zotero.org/groups/945096/items/TN6HMC9D"],"itemData":{"id":350,"type":"book","title":"Health Implications of Perchlorate Ingestion","publisher":"National Academies Press","publisher-place":"Washington, DC","event-place":"Washington, DC","author":[{"literal":"National Research Council (NRC)"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Additionally, the NRC concluded that the most sensitive population to perchlorate exposure are “the fetuses of pregnant women who might have hypothyroidism or iodide deficiency” (p. 178). The EPA established a reference dose (RfD) consistent with the NRC’s recommended RfD of 0.7 μg/kg/day for perchlorate. The reference dose is an estimate of a human’s daily exposure to perchlorate that is likely to be without an appreciable risk of adverse effects. This RfD was based on a study [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a3u94lt6me","properties":{"formattedCitation":"(Greer, Goodman, Pleus, & Greer, 2002)","plainCitation":"(Greer, Goodman, Pleus, & Greer, 2002)","noteIndex":0},"citationItems":[{"id":387,"uris":["http://zotero.org/groups/945096/items/

6AKUNIX6"],"uri":["http://zotero.org/groups/945096/items/6AKUNIX6"],"itemData":{"id":387,"type":"article-journal","title":"Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans","container-title":"Environmental Health Perspectives","page":"927","volume":"110","issue":"9","author":[{"family":"Greer","given":"Monte A."},{"family":"Goodman","given":"Gay"},{"family":"Pleus","given":"Richard C."},{"family":"Greer","given":"Susan E."}],"issued":{"date-parts":[["2002"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] of perchlorate's inhibition of radioactive iodine uptake in healthy adults and the application of an uncertainty factor of 10 for intraspecies variability [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"0oHz805e","properties":{"formattedCitation":"(USEPA, 2005b)","plainCitation":"(USEPA, 2005b)","noteIndex":0},"citationItems":[{"id":980,"uris":["http://zotero.org/groups/945096/items/LHANJBR6"],"uri":["http://zotero.org/groups/945096/items/LHANJBR6"],"itemData":{"id":980,"type":"article","title":"Integrated Risk Information System (IRIS) Chemical Assessment Summary: Perchlorate (ClO4-) and Perchlorate Salts","publisher":"USEPA National Center for Environmental Assessment","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

In October 2008, the EPA published a preliminary regulatory determination to not regulate perchlorate in drinking water and requested public comment (73 FR 60262). In that preliminary determination, the EPA found that perchlorate did not occur with a frequency and at levels of public health concern and that development of a regulation did not present a meaningful opportunity for health risk reduction for persons served by public water systems. The EPA derived and used a Health Reference Level (HRL) of 15 μg/L based on the RfD of 0.7 μg/kg/day and body weight and exposure information for pregnant women in making this conclusion [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"FZ6WMtAv","properties":{"formattedCitation":"(USEPA, 2008a)","plainCitation":"(USEPA, 2008a)","noteIndex":0},"citationItems":[{"id":934,"uris":["http://zotero.org/groups/945096/items/HBX88QM9"],"uri":["http://zotero.org/groups/945096/items/HBX88QM9"],"itemData":{"id":934,"type":"article-journal","title":"Drinking water: Preliminary regulatory determination on perchlorate","container-title":"Federal Register","volume":"73","issue":"198","abstract":"SUMMARY: This action presents EPA's preliminary regulatory determination for perchlorate in accordance with the Safe Drinking Water Act (SDWA). The Agency has determined that a national primary drinking water regulation (NPDWR) for perchlorate would not present \"a meaningful opportunity for health risk reduction for persons served by public water systems." The SDWA requires EPA to make determinations every five years of whether to regulate at least five contaminants on the Contaminant Candidate

List (CCL). EPA included perchlorate on the first and second CCLs that were published in the Federal Register on March 2, 1998 and February 24, 2005. Most recently, EPA presented final regulatory determinations regarding 11 contaminants on the second CCL in a notice published in the Federal Register on July 30, 2008. In today's action, EPA presents supporting rationale and requests public comment on its preliminary regulatory determination for perchlorate. EPA will make a final regulatory determination for perchlorate after considering comments and information provided in the 30-day comment period following this notice. EPA plans to publish a health advisory for perchlorate at the time the Agency publishes its final regulatory determination to provide State and local public health officials with technical information that they may use in addressing local contamination.","ISSN":"ISSN 0097-6326 EISSN 2167-2520","shortTitle":"Federal Register","journalAbbreviation":"Fed. Reg.","language":"English","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2008"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Using the UCMR 1 occurrence data, the EPA estimated that less than 1% of drinking water systems (serving approximately 1 million people) had perchlorate levels above the HRL of 15 μg/L. Based on this information the EPA found that perchlorate did not occur at a frequency and at levels of public health concern. The EPA also determined there was not a meaningful opportunity for a NPDWR for perchlorate to reduce health risks.

In August 2009, the EPA published a supplemental request for comment with new analysis that derived potential alternative Health Reference Levels (HRLs) for 14 life stages, including infants and children. The analysis used the RfD of 0.7 μg/kg/day and life stage-specific bodyweight and exposure information, resulting in comparable perchlorate concentrations in drinking water, based on life stage, of between 1 μg/l to 47 μg/l (74 FR 41883; USEPA, 2009).

In February 11, 2011, the EPA published its determination to regulate perchlorate (76 FR 7762; USEPA, 2011) after careful consideration of public comments on the October 2008 and August 2009 notices. The EPA found at that time that perchlorate may have an adverse effect on the health of persons, it is known to occur in public drinking water systems with a frequency and at levels that present a public health concern, and regulation of perchlorate presented a meaningful opportunity for health risk reduction for persons served by public water systems. The EPA stated then that: "*Based on the data in Table 1 and the range of potential alternative HRLs, EPA has determined that perchlorate is known to occur or there is a substantial likelihood that it will occur with a frequency and at levels of public health concern.*"(USEPA, 2011, p. 7765). The EPA found that as many as 16 million people could potentially be exposed to perchlorate at levels of concern, up from 1 million people originally estimated in the 2008 notice.

As a result of the determination, and as required by the SDWA, section 1412(b)(1)(E), the EPA initiated the process to develop a MCLG and a NPDWR for perchlorate.

In September 2012, the U.S. Chamber of Commerce (the Chamber) submitted to the EPA a Request for Correction under the Information Quality Act regarding the EPA's regulatory determination. In the request, the Chamber claimed that the UCMR 1 data used in the EPA's occurrence analysis did not comply with data quality guidelines and were not representative of current conditions. In response to this request, the EPA reassessed the data and removed certain source water samples that could be paired with appropriate follow-up samples located at the entry point to the distribution system. The EPA also updated the UCMR 1 data in the analysis for systems in California and Massachusetts, using state compliance data to reflect current occurrence conditions after state regulatory limits for perchlorate were implemented.

As required by section 1412(d) of the SDWA, as part of the NPDWR development process, the EPA requested comments from the Science Advisory Board (SAB) in 2012, seeking guidance on how best to consider and interpret the life stage information, the epidemiologic and biomonitoring data since the NRC report, physiologically-based pharmacokinetic (PBPK) analyses, and the totality of perchlorate health information to derive an MCLG for perchlorate. In May 2013, the SAB recommended that the EPA:

- derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling based upon its mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters;
- expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;

- utilize a mode-of-action framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition—to thyroid hormone changes—and finally to neurodevelopmental impacts; and
- ''Extend the [BBDR] model expeditiously to . . . provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages''(SAB for the U.S. EPA, 2013, p. 19).

To address the SAB recommendations, the EPA revised an existing PBPK/PD model that describes the dynamics of perchlorate, iodide, and thyroid hormones in a woman during the third trimester of pregnancy (Lumen, Mattie, & Fisher, 2013; USEPA, 2009b). The EPA also created its own Biologically Based Dose Response (BBDR) models that included the additional sensitive life stages identified by the SAB, *i.e.,* breast- and bottle-fed neonates and infants (SAB for the U.S. EPA, 2013, p. 19).

To determine whether the Agency had implemented the SAB recommendations for modeling thyroid hormone changes, the EPA convened an independent peer review panel to evaluate the BBDR models in January 2017 (External Peer Reviewers for USEPA, 2017). The EPA considered the recommendations from the 2017 peer review and made necessary model revisions to increase the scientific rigor of the model and the modeling results.

The EPA convened a second independent peer review panel in January 2018 to evaluate the revisions to the BBDR model. The EPA also presented several approaches to link the thyroid hormone changes in a pregnant mother predicted by the BBDR model to neurodevelopmental effects using evidence from the epidemiological literature (External Peer Review for U.S. EPA, 2018).

In response to a lawsuit brought to enforce the deadlines in the SDWA, section 1412(b)(1)(E), on October 18, 2016, the U.S. District Court for the Southern District of New York entered a consent decree, requiring the EPA to sign for publication a proposal for a MCLG and NPDWR for perchlorate in drinking water no later than October 31, 2018, and to sign for publication a final MCLG and NPDWR for perchlorate in drinking water no later than December 19, 2019. The deadline for the EPA to propose a MCLG and NPDWR for perchlorate in drinking water was later extended to May 28, 2019, and the date for signature of a final MCLG and NPDWR was extended to be no later than June 19, 2020. The consent decree is available in the docket for this action.

In compliance with the deadline established in the consent decree, on May 23, 2019, the EPA Administrator signed a proposed rulemaking notice seeking public comment on a range of options regarding the regulation of perchlorate in public drinking water systems. The proposed rulemaking notice was published in the *Federal Register* on June 26, 2019. 84 Fed. Reg. 30524. The EPA proposed a NPDWR for perchlorate with an MCL and MCLG of 56 μg/L. The proposed MCLG of 56 μg/L was based on avoiding a 2 point IQ decrement associated with exposure to perchlorate in drinking water during the most sensitive life stage (the fetus) within a specific segment of the population (iodine deficient pregnant women).

The EPA also requested comment on two alternative MCL/MCLG values of 18 µg/L and 90 µg/L. These alternatives were based upon avoiding 1 point and 3 point IQ decrements respectively, associated with perchlorate exposure. Additionally, the EPA requested comment on whether the 2011 regulatory determination should be withdrawn, based on new information including updated occurrence data on perchlorate in drinking water and new analysis of the concentration of perchlorate in drinking water that represents a level of health concern.

III. Withdrawal of the 2011 Regulatory Determination and Final Determination to Not Regulate Perchlorate

In determining whether to regulate a particular contaminant, the EPA must follow the criteria mandated by the 1996 SDWA Amendments. Specifically, in order to issue a MCLG and NPDWR for perchlorate, the EPA must determine that perchlorate "may have an adverse effect on the health of persons," that perchlorate occurs at "a frequency and at levels of public health concern" in public water systems, and that regulation of perchlorate in drinking water systems "presents a meaningful opportunity for health risk reduction for persons served by public water systems." The SDWA, section 1412(b)(1)(A). In preparing the 2019 proposal for perchlorate, the EPA updated and improved information on the levels of public health concern and the frequency and levels of perchlorate in public water systems. The following is the EPA's reassessment of the regulatory determination criteria applied to the best available health science and occurrence data for perchlorate.

A. May perchlorate have an adverse effect on the health of persons?

Yes, perchlorate may have adverse health effects. The perchlorate anion is biologically significant specifically with respect to the functioning of the thyroid gland. Perchlorate can interfere with the normal functioning of the thyroid gland by inhibiting the transport of iodide into the thyroid, resulting in a deficiency of iodide in the thyroid. Perchlorate inhibits (or blocks) iodide transport into the thyroid by chemically competing with iodide, which has a similar shape and electric charge. The transfer of iodide from the blood into the thyroid is an essential step in the synthesis of thyroid hormones. Thyroid hormones play an important role in the regulation of metabolic processes throughout the body and are also critical to developing fetuses and infants, especially for brain development. Because the developing fetus depends on an adequate supply of maternal thyroid hormones for its central nervous system development during the first and second trimester of pregnancy, iodide uptake inhibition from perchlorate exposure has been identified as a concern in connection with increasing risk of neurodevelopmental impairment in fetuses of pregnant women with low dietary iodine. Poor iodide uptake and subsequent impairment of the thyroid function in pregnant and lactating women have been linked to delayed development and decreased learning capability in their infants and children (NRC, 2005). Therefore, the EPA continues to find that perchlorate may have an adverse effect on the health of persons.

B. Is perchlorate known to occur or is there a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern?

The EPA has determined that perchlorate does not occur with a frequency and at levels of public health concern in public water systems. The EPA has made this determination by comparing the best available data on the occurrence of perchlorate in public water systems to potential MCLGs for perchlorate.

In past regulatory determinations, the EPA has identified HRLs as benchmarks against which the EPA compares the concentration of a contaminant found in public water systems to determine if it occurs at levels of public health concern. For the 2011 regulatory determination the EPA identified potential HRLs values ranging from 1 to 47 μg/L for 14 different life stages. These HRLs were not final decisions about the level of perchlorate in drinking water that is without adverse effects. For the 2019 proposal, the EPA derived three potential MCLGs for perchlorate of 18, 56, and 90 μg/L for the most sensitive life stage using the best available peer reviewed science in accordance with the SDWA. After considering public comment, the EPA used these potential MCLGs as the levels of public health concern in assessing the frequency of occurrence of perchlorate in this regulatory determination. These MCLGs were set at levels to avoid IQ decrements of 1, 2, and 3 points respectively in the most sensitive life stage, the children of hypothyroxinemic women with low iodine intake. The EPA proposed an MCLG of 56 μg/L and alternative MCLG values of 18 and 90 μg/L.

The rationale used in deriving the numerical values is presented in greater detail in the EPA's technical support document titled "Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (USEPA, 2019b).

The EPA compared these potential MCLG values to the updated perchlorate UCMR 1 occurrence data set. A comprehensive description of the perchlorate occurrence data is presented in Section VI of the 2019 proposal. It is also available in the "Perchlorate Occurrence and Monitoring Report" (USEPA, 2019a).

The occurrence data for perchlorate were collected from 3,865 PWSs between 2001 and 2005 under the UCMR 1. In the 2019 proposal, the EPA modified the UCMR 1 data set in response to concerns raised by stakeholders regarding the data quality and to represent current conditions in California and Massachusetts, which have enacted perchlorate regulations since the UCMR 1 data were collected. Massachusetts promulgated a drinking water standard for perchlorate of 2 μg/L in 2006 [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"8DPpSrv3","properties":{"formattedCitation":"(MassDEP, 2006)","plainCitation":"(MassDEP, 2006)","noteIndex":0},"citationItems":[{"id":151,"uris":["http://zotero.org/groups/945096/items/9893MBZH"],"uri":["http://zotero.org/groups/945096/items/9893MBZH"],"itemData":{"id":151,"type":"personal_communication","title":"Letter to Public Water Suppliers concerning new perchlorate regulations","URL":"https://www.mass.gov/lists/perchlorate-background-information-and-standards#perchlorate---final-standards-","author":[{"literal":"MassDEP"}],"issued":{"date-parts":[["2006"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], and California promulgated a drinking water standard of 6 μg/L in 2007 [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"cfr6HNhg","properties":{"formattedCitation":"(California Department of Public

Health, 2007)","plainCitation":"(California Department of Public Health, 2007)","noteIndex":0},"citationItems":[{"id":150,"uris":["http://zotero.org/groups/945096/items/RA45NKLQ"],"uri":["http://zotero.org/groups/945096/items/RA45NKLQ"],"itemData":{"id":150,"type":"personal_communication","title":"State Adoption of a Perchlorate Standard","URL":"https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/perchlorate/AdoptionMemotoWaterSystems-10-2007.pdf","author":[{"literal":"California Department of Public Health"}],"issued":{"date-parts":[["2007"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Systems in these states are now required to keep perchlorate levels in drinking water below their state limits. As discussed below, the EPA finds that perchlorate levels in drinking water and sources of drinking water have decreased since the UCMR 1 data collection. The main factors contributing to the decrease in perchlorate levels are the promulgation of drinking water regulations for perchlorate in California and Massachusetts and the ongoing remediation efforts in the state of Nevada to address perchlorate contamination in groundwater adjacent to the lower Colorado River upstream of Lake Mead.

To update the occurrence data for systems sampled during UCMR 1 from California and Massachusetts, the EPA identified all systems and corresponding entry points which had reported perchlorate detections in UCMR 1. Once the systems and entry points with detections were appropriately identified, the EPA then used a combination of available data from Consumer Confidence Reports (CCRs) and perchlorate compliance monitoring data from California (https://sdwis.waterboards.ca.gov/PDWW/) and Massachusetts (https://www.mass.gov/service-details/public-water-supplier-document-search) to match current compliance monitoring data (where available) to the corresponding water systems and entry points sampled during UCMR 1.

The EPA has determined that the UCMR 1 data with these updates are the best available data collected in accordance with accepted methods regarding the frequency and level of perchlorate nationally. The UCMR 1 data are from a census of the large water systems (serving more than 10,000 people) and a statistically representative sample of small water systems that provides the best available, national assessment of perchlorate occurrence in drinking water.

The EPA used entry point maximum measurements to estimate potential baseline occurrence and exposure at levels that exceed the potential MCLG thresholds. The maximum measurements indicate highest perchlorate levels reported in at least one quarterly sample from surface water systems and at least one semi-annual sample from ground water systems.

Table 1: Perchlorate Occurrence and Exposure (Updated UCMR 1 Data Set)

Threshold Concentration (μg/L)	Entry Points with Detections above Threshold	Water Systems with Detections above Threshold	Percent of U.S. Water Systems with Detections above Threshold	Population Served
18 μg/L	17	15	0.03 %	620,560
56 μg/L	2	2	0.004 %	32,432
90 μg/L	1	1	0.002 %	25,972

Table 1 presents the number and percentage of water systems that reported perchlorate at levels exceeding the three proposed MCLG threshold concentrations. In summary, the updated perchlorate occurrence information suggests that at an MCLG of 18 μg/L, there would be 15 systems (0.03% of all water systems in the U.S.) that would exceed the threshold, at an MCLG of 56 μg/L, two systems (0.004% of all water systems in the U.S.) would exceed the threshold, and finally one system would exceed the MCLG threshold of 90 μg/L. Based on the analysis of drinking water occurrence presented in the 2019 proposal and the data summarized in Table 1 and the range of potential MCLGs, the EPA concludes that perchlorate does not occur with a frequency and at levels of public health concern in public water systems.

While the EPA has made its conclusion that perchlorate does not occur at a frequency and at levels of public health concern in public water systems based on the updated UCMR 1 data, the EPA also sought to find additional information about the perchlorate levels at the 15 water systems that had at least one reported result greater than 18 μg/L in the updated UCMR 1 data. The EPA found that perchlorate levels have been reduced at many of these water systems. Although these water systems were not required to take actions to reduce perchlorate in drinking water, many had conducted additional monitoring for perchlorate and found decreased levels or had taken mitigation efforts to address perchlorate, confirming the EPA's conclusion described above. The status of each of these systems is described in Table 2 below.

Table 2: Update on Systems with Perchlorate levels above 18 μg/L in the UCMR 1

State	**System Name**	**Range of UCMR 1 Results (µg/L)****	**Update on Mitigation and Levels of Perchlorate**++
Florida	Sebring Water	ND-70	The EPA contacted the Sebring system in January 2020. Operations personnel indicated that no follow-up/updated monitoring data for perchlorate are available.
Florida	Manatee County Utilities Dept	ND-30	Researchers contacted the system to identify the source of perchlorate. System personnel attributed the sole perchlorate detection under UCMR 1 to analytical error. System personnel indicated that three other quarterly samples collected under UCMR 1 as well as other subsequent perchlorate sampling efforts were non-detect. Source: AWWA (2008)
Georgia	Oconee Co.-Watkinsville	38 (single sample)	Researchers contacted the system and found that a perchlorate contaminated well was removed from service in 2003. The system indicates that perchlorate is no longer detected. Source: Luis et al. (2019)
Louisiana	St. Charles Water District 1 East Bank	ND-24	The EPA was not able to identify updated data on perchlorate levels for this system.
Maryland	City of Aberdeen	ND-19	The system's 2018 Consumer Confidence Report (CCR) indicates that perchlorate was not detected. According to the Maryland Department of Environment, perchlorate was not detected in this system in 2019. In addition, researchers contacted the system and found that there has been no detection of perchlorate since treatment was installed in 2009. Source: Luis et al. (2019)
Maryland	Chapel Hill - Aberdeen Proving Grounds	ND-20	The EPA contacted the Chapel Hill System in January 2020. Water system personnel indicate that the Chapel Hill WTP was taken off-line and was replaced with a new treatment plant and five new production wells. The new treatment plant started operations on January 27, 2020. System personnel

State	System Name	Range of UCMR 1 Results (µg/L)**	Update on Mitigation and Levels of Perchlorate++
			also indicate that monitoring was conducted in November 2019 and perchlorate was not detected in either the source well water or the finished water. In addition, according to the Maryland Department of Environment, perchlorate was not detected in this system in 2019.
Mississippi	Hilldale Water District	ND-20	The EPA contacted the Hilldale System in January 2020. Water system personnel indicated that no follow-up/updated monitoring data for perchlorate are available.
New Mexico	Deming Municipal Water System	15-20	Data from the EPA's SDWIS/FED database indicates that the entry point that reported detections in UCMR 1 (Well #3) is now inactive (i.e., the contaminated source is no longer in use).
Nevada	City of Henderson	6-23	Researchers report that the perchlorate levels described in the system's CCR ranged from non-detect to 9.7 µg/L. Source AWWA (2008).
Ohio	Fairfield City PWS	6-27	The EPA contacted the Fairfield City System in January 2020. Water system personnel indicated that follow-up monitoring was conducted after UCMR 1, between 2002 and 2004. The Ohio EPA provided copies of the follow-up monitoring results which indicate that results at the entry point ranged from non-detect to 13 µg/L.
Ohio	Hecla Water Association-Plant PWS	ND-32	The EPA contacted the Hecla Water Association System in January 2020. Water system personnel indicated that that no follow-up/updated monitoring data for perchlorate are available.
Oklahoma	Enid	ND-30	The EPA reviewed Oklahoma's monitoring data and did not find any monitoring results reported for perchlorate.

State	**System Name**	**Range of UCMR 1 Results (µg/L)**[**]	**Update on Mitigation and Levels of Perchlorate**[++]
Pennsylvania	Meadville Area Water Authority	ND-33	The EPA contacted the Meadville System in January 2020. Water system personnel indicated that no follow-up/updated monitoring data for perchlorate are available.
Puerto Rico	Utuado Urbano	ND-420	The EPA contacted the Puerto Rico Aqueduct and Sewer Authority (PRASA) in January 2019. PRASA personnel indicated that no updated monitoring data for perchlorate are available. *NOTE: The PRASA personnel stated that the Utuado water system was significantly impacted by hurricane Maria and monitoring records from years prior to 2017 were lost.*
Texas	City of Levelland	ND-32	Researchers found that a water storage tank was the source of perchlorate contamination, the wells feeding the tank were tested by the state and perchlorate was not detected. The water tank was shut off from service. Source: Luis et al. (2019).

** - Values have been rounded. ND describes a sampling event where perchlorate was not detected at or above the UCMR 1 minimum reporting level of 4 µg/L. UCMR 1 results collected between 2001 and 2005.

++ - To obtain updated data and/or information regarding perchlorate levels, the EPA reviewed Consumer Confidence Reports and other publicly available data, as well as published studies. In addition, the EPA contacted some water systems for information about current perchlorate levels. (USEPA, 2020b)

C. Is there a meaningful opportunity for the reduction of health risks from perchlorate for persons served by public water systems?

The EPA's analysis presented in the 2019 proposal demonstrates that a NPDWR for perchlorate does not present a meaningful opportunity for health risk reduction for persons served by public water systems. As discussed above, the EPA found that perchlorate occurs with very low frequency at levels of public health concern. Based on updated UCMR 1 occurrence information, there were 15 water systems (0.03% of all water systems in the U.S.) that detected perchlorate in drinking water above the lowest proposed alternative MCLG of 18 μg/L and only 1 system had a detection above the proposed alternative MCLG of 90 μg/L. Specifically, Table 1 presents the population served by PWSs that were monitored under UCMR 1 for which the highest reported perchlorate concentration was greater than the identified thresholds. The EPA estimates[2] that the number of people who may be potentially consuming water containing perchlorate at levels that could exceed the levels of concern for perchlorate could range between 26,000 and 620,000. The small number of water systems with perchlorate levels greater than identified thresholds and the corresponding small population served provides ample support for the EPA's conclusion that the regulation of perchlorate does not present a "meaningful opportunity for health risk reduction for persons served by public water systems," within the meaning of the SDWA, section 1412(b)(1)(A)(iii).

The EPA also considered the findings of the Health Risk Reduction and Cost Analysis (HRRCA, USEPA 2019c) as additional information supporting withdrawal of the regulatory determination. The HRRCA for perchlorate (which was presented in the 2019 proposal) provides a unique set of economic data indicators that are not available for regulatory determinations

[2] The values shown in Table 1 are based on the revised UCMR 1 data. The EPA also applied statistical sampling weights to the small systems results to extrapolate to national results. There was one small system included in the statistical sample stratum which had a perchlorate measurement exceeding 18 μg/L. Accordingly, the EPA estimates that approximately 41,000 small system customers may be exposed to perchlorate greater than 18 μg/L.

because the HRRCA is required for a proposed NPDWR under SDWA Section 1412(b)(3)(C), but is not required to support a regulatory determination. Accordingly, because the EPA initially determined that perchlorate met the criteria for regulation and began the regulatory analysis process, the HRRCA was available with respect to perchlorate, and the Agency considered this comprehensive economic analysis in informing its decision to withdraw the regulatory determination.

Specifically, the HRRCA provides a description of the potential benefits and costs of a drinking water regulation for perchlorate. For all potential regulatory levels considered for perchlorate (18, 56, and 90 μg/L) the total costs associated with establishing a regulation were substantially higher than the potential range of benefits. The infrequent occurrence of perchlorate at levels of health concern imposes high monitoring and administrative cost burdens on public water systems and the states, while having little impact on health risk reductions and the associated low estimates of benefits.

Based on a comparison of costs and benefits estimated at the three potential regulatory levels, the EPA determined in the 2019 proposal that the benefits of establishing a drinking water regulation for perchlorate do not justify the potential costs.

A drinking water regulation for perchlorate would impose significant burden on states and water systems, mainly associated with requirements for monitoring but which would result in very few systems having to take action to reduce perchlorate levels. It is of paramount importance that water systems (particularly medium, small and economically distressed systems)

focus their limited resources on actions that ensure compliance with existing NPDWRs and maintain their technical, managerial, and financial capacity to improve system operations and the quality of water being provided to their customers rather than spending resources monitoring for contaminants that are unlikely to occur.

D. What is the EPA's final regulatory determination on perchlorate?

Based on the EPA's analysis of the best available public health information, and after careful review and consideration of public comments on the June 2019 proposal, the Agency is withdrawing its 2011 determination and is making a final determination to not regulate perchlorate. Accordingly, the EPA will not issue a NPDWR for perchlorate at this time. While the EPA has found that perchlorate may have an adverse effect on human health, based on the analysis presented in this notice and supporting record, the EPA has determined that perchlorate does not occur in public water systems with a frequency and at levels of public health concern and that regulation of perchlorate does not present a meaningful opportunity to reduce health risks for persons served by public water systems. This conclusion is based on the best available peer reviewed science and data collected in accordance with accepted methods on perchlorate health effects and occurrence.

IV. Summary of Key Public Comments on Perchlorate

The EPA received approximately 1,500 comments from individuals or organizations on the June 2019 proposal. This section briefly discusses the key technical issues raised by commenters and the EPA's response. Comments are also addressed in the ''Comment Response

Document for the Final Regulatory Action for Perchlorate'' (USEPA, 2020a) available at http://www.regulations.gov (Docket ID No. EPA–HQ–OW–2018–0780).

A. SDWA Statutory Requirements and the EPA's Authority

The EPA received comments stating the Agency should promulgate an MCLG and MCL for perchlorate and comments stating the Agency should not promulgate a regulation. After considering these comments the EPA has re-evaluated perchlorate in accordance with the SDWA, section 1412(b)(1)(A), which requires that the Agency promulgate a NPDWR if (i) the contaminant may have an adverse effect on the health of persons; (ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and (iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

The EPA has determined, based upon the best available peer reviewed science and data collected in accordance with accepted methods, that perchlorate does not occur at a frequency and at levels of public health concern, and that regulation of perchlorate does not present a meaningful opportunity for health risk reduction. Because perchlorate does not meet the statutory criteria for regulation, the EPA lacks the authority to issue a MCLG or NPDWR for perchlorate, and is therefore withdrawing its 2011 regulatory determination and issuing this final determination to not regulate perchlorate. For more information regarding EPA's statutory authority to withdraw its regulatory determination, see Section II.C above.

B. Health Effects Assessment

Health Effects/MCLG Derivation

The EPA received comments indicating that the Agency should utilize different approaches to derive the MCLG for perchlorate including approaches that some states used to develop their perchlorate advisory levels or drinking water standards. The EPA considered a number of alternative approaches to develop the MCLG for perchlorate and in accordance with the SDWA, section 1412(e), the Agency sought recommendations from the Science Advisory Board. The EPA derived the proposed MCLG for perchlorate based on the approach recommended by the Science Advisory Board (SAB) (SAB for the U.S. EPA, 2013). The SAB recommended that *"the EPA derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling based upon its mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters."* The EPA has implemented these recommendations and has obtained two independent peer reviews of the analysis. These peer reviewers stated that: "*Overall, the panel agreed that the EPA and its collaborators have prepared a highly innovative state-of-the-science set of quantitative tools to evaluate neurodevelopmental effects that could arise from drinking water exposure to perchlorate. While there is always room for improvement of the models, with limited additional work to address the committee's comments below, the current models are fit-for-purpose to determine an MCLG*" (External Peer Reviewers for USEPA, 2018, p. 2).

The EPA received comments indicating the most sensitive life stages were not selected and/or considered in the Agency's approach. The EPA disagrees. Gestational exposure to perchlorate during neurodevelopment is the most sensitive time period. The NRC concluded that the population most sensitive to perchlorate exposure are "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a1mn5hjprkt","properties":{"formattedCitation":"(National Research Council (NRC), 2005b)","plainCitation":"(National Research Council (NRC), 2005b)","noteIndex":0},"citationItems":[{"id":350,"uris":["http://zotero.org/groups/945096/items/TN6HMC9D"],"uri":["http://zotero.org/groups/945096/items/TN6HMC9D"],"itemData":{"id":350,"type":"book","title":"Health Implications of Perchlorate Ingestion","publisher":"National Academies Press","publisher-place":"Washington, DC","event-place":"Washington, DC","author":[{"literal":"National Research Council (NRC)"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. In addition, there is clear evidence that disrupted maternal thyroid hormone levels during gestation can impact neurodevelopment later in life (Alexander et al., 2017; Costeira et al., 2011; Endendijk et al., 2017; Ghassabian, Bongers-Schokking, Henrichs, Jaddoe, & Visser, 2011; Glinoer & Delange, 2000; Glinoer & Rovet, 2009; Gyllenberg et al., 2016; Henrichs et al., 2010; Korevaar et al., 2016; Morreale de Escobar, Obregón, & Escobar del Rey, 2004; Noten et al., 2015; Pop et al., 2003, 1999;

SAB for the U.S. EPA, 2013; Thompson et al., 2018; van Mil et al., 2012; Wang et al., 2016; Zoeller & Rovet, 2004; Zoeller et al., 2007). The available data demonstrate that the fetus of the first trimester pregnant mother, when compared to other life-stages, experiences the greatest impact from the same dose of perchlorate, which is described in detail in Section 6 of the document "Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (USEPA, 2019a). Some commenters suggested that the bottle-fed infant is a more sensitive life-stage. The EPA disagrees as described in the January 2017 Peer Review Report on the original Biologically Based Dose Response (BBDR) model, the bottle-fed infant's thyroid hormone levels were not impacted by doses of perchlorate up to 20 μg/day (External Peer Reviewers for USEPA, 2017). This lack of any impact is due primarily to the iodine in the formula, which offsets the impact of perchlorate on the thyroid.

The EPA received comments advocating for the use of the population-based approach evaluating the shift in the proportion of a population that would fall below a hypothyroxinemic cut point under a perchlorate exposure scenario. The EPA chose to develop the MCLG using dose-response functions from the epidemiological literature to estimate neurodevelopmental impacts in the offspring of pregnant women exposed to perchlorate. The EPA selected this proposed approach because it is consistent with the SDWA's definition of a MCLG to avoid adverse health effects and because it is most consistent with the SAB recommendations. In addition, the fact that thyroid hormone levels vary by reference population and that there is not a defined value representing hypothyroxinemia makes the population-based approach less desirable than the approach selected (USEPA, 2018).

End Point Selection/Basis

The EPA received comments regarding the magnitude of an IQ change which should be used in deriving the MCLG. The EPA's proposed MCLG was based upon avoiding a 2% change in IQ in the most sensitive life stage and the EPA also requested comment on alternative options for the MCLG that would respectively avoid 1% or 3% change in IQ in the most sensitive life stage. Many comments stated that the EPA should at most consider a 1% IQ change. However, several commenters stated a 3% change is too small to have a meaningful impact and suggested the EPA consider a higher IQ percent change.

The EPA uses a variety of science policy approaches to select points of departure for developing regulatory values. For instance, in noncancer risk assessment the EPA often uses a percentage change in value. When assessing toxicological data, a 10 % extra risk (for discrete data), or a 1 standard deviation (i.e., 15 IQ points) change from the mean (for continuous data) is often used (USEPA, 2012). A smaller response to inform a POD has been applied when using epidemiological literature because there is an inherently more direct relationship between the study results and the exposure context and health endpoint.

Given the difficulty in identifying a response below which no adverse impact occurs when considering a continuous outcome in the human population, the EPA looked to its Benchmark Dose Guidance (2012) for insight regarding a starting point. Specifically, ''[a] BMR of 1% has typically been used for quantal human data from epidemiology studies'' (p. 21, USEPA, 2012). For the specific context of setting an MCLG for perchlorate, the EPA evaluated the level of perchlorate in water associated with a 1% decrease, a 2% decrease, and a 3 percent decrease in the mean population IQ (i.e., 1, 2 and 3 IQ points).

In evaluating the frequency and level of occurrence of perchlorate in drinking water the EPA has found that perchlorate does not occur with frequency even at the lowest alternative MCLG of 18 μg/L which is based upon avoiding a 1% change in IQ in the most sensitive life stage.

The EPA received comments that the proposed MCLG did not incorporate an adequate margin of safety to comply with the SDWA. The EPA disagrees that it failed to use an adequate margin of safety. The EPA's assessment focused upon the most sensitive subset of the population, specifically offspring whose mothers had low (75 μg/day) iodine intake and were hypothyroxinemic (fT4 in the lowest 10th percentile of the population). In addition, to account for uncertainties and to ensure the most sensitive subset of the population is protected with an adequate margin of safety, a 3-fold uncertainty factor was applied to the proposed MCLG calculation (USEPA, 2019a). More discussion on the uncertainty factor is presented in the section "Consideration of Uncertainties."

The EPA received some comments stating that the selection of the study for informing the relationship between maternal hormone levels (fT4) and IQ was inadequately described. Other comments supported the EPA's study selection. The EPA concludes that selection of the Korevaar et al. (2016) study is appropriate because that study provides the most robust data available with a clear measure of neurodevelopment that can be expressed as a function of changing maternal fT4 exposure, which is necessary to the development of the model.

BBDR and PBPK Models

The EPA received comments indicating the BBDR model was not transparent, scientifically valid, or based on robust data. The EPA disagrees. The model represents the best available peer reviewed science and uses the best available data to inform a MCLG for perchlorate. The EPA does not believe there is a significant lack of transparency with respect to the assumptions related to the BBDR model. Appendix A of the EPA's Proposed MCLG Approaches report outlines the justification for all assumptions used in the development of the BBDR model (USEPA, 2019a). The EPA also disagrees with the assertion the BBDR model is far too uncertain to be relied upon as the basis for the derivation of the RfD. The EPA has used the best available science to calibrate the pharmacokinetic aspects of the BBDR model. The development of the BBDR model was in response to SAB recommendations and a model was deemed to be a more refined approach to estimating a dose-response relationship between perchlorate exposure and maternal fT4 than anything that was available in the current scientific literature. The EPA disputes the claim that there are issues with the scientific validity of the BBDR model as the Agency conducted a peer review of the approach proposed and the reviewers stated the approach was "fit for purpose" to inform a MCLG for perchlorate (External Peer Reviewers for U.S. EPA, 2018, p. 2).

Consideration of Uncertainties

The EPA received comments on the Agency's use of Uncertainty Factors (UFs); with most commenters suggesting that the EPA should consider a higher UF. The EPA thoroughly considered the application of UFs when deriving the RfDs and followed guidance presented in "A review of the reference dose and reference concentration processes" (USEPA, 2002). The EPA concluded that the UFs are adequately justified and subsequently no changes have been made. Justification for each of the UFs can be found in Section 11 of the Agency's MCLG Derivation report (USEPA, 2019a).

The EPA selected a UF of 3 for inter-individual variability because the Agency specifically modeled groups within the population that are identified as likely to be at greater risk of the adverse effects from perchlorate in drinking water (i.e., the fetus of the iodide deficient pregnant mother). The EPA selected model parameters to account for the most sensitive individuals in that group (i.e., muted TSH feedback, low fT4 values, low-iodine intake). As discussed in the MCLG Derivation report, the EPA has attempted to select the most appropriate inputs to protect the most sensitive population with an adequate margin of safety (USEPA, 2019a). The EPA has determined that the selection of a UF of 3 for inter-individual variability is justified. As described in the MCLG Derivation report, because the output from the BBDR model is specific to the sensitive population the EPA concluded that the UF of 3 is appropriate. In regards to variation in sensitivity among the members of the human population (i.e., inter-individual variability), section 4.4.5.3 of the EPA guidance "A review of the reference dose and reference concentration process" (USEPA, 2002) document states, "In general, the Technical Panel reaffirms the importance of this UF, recommending that reduction of the intraspecies UF from a default of 10 be considered only if data are sufficiently representative of the exposure/dose-response data for the most susceptible subpopulation(s). Similar to the interspecies UF, the intraspecies UF can be considered to consist of both a toxicokinetic and toxicodynamic portion (i.e. 10^0.5 each)" (USEPA, 2002). Given that the BBDR model significantly accounts for differences within the human population, the full UF of 10 is not warranted.

One commenter suggested using a UF greater than 1 to account for the extrapolation of the lowest-observed adverse effect level (LOAEL) to the no-observed-adverse-effect-level (NOAEL). LOAELs and NOAELs were not identified or used by the EPA in its assessment because the Agency employed a sophisticated BBDR modeling approach, which was coupled with extrapolation to changes in IQ using linear regression, to determine a POD that would not be expected to represent an adverse effect. Therefore, a UF of 1 is appropriate. Other commenters suggested incorporating UFs for database deficiencies. Based on the findings of the NRC report, the EPA has previously concluded that this UF was not needed for deficiencies in the perchlorate database (NRC, 2005; USEPA, 2005a). The EPA believes that a UF of 1 to account for database deficiencies is still appropriate given that the state of the perchlorate database has only increased since 2005.

C. Occurrence Analysis

The EPA received comments suggesting that the revised UCMR 1 data did not provide an adequate estimate of the perchlorate occurrence in drinking water systems. Some commenters indicated that the age of the collected data rendered the occurrence analysis obsolete and overestimated, since it no longer captures current lower contamination conditions that have been achieved due to mitigation measures taken in the Colorado River Basin. Other commenters criticized the EPA for replacing UCMR 1 data with compliance data for the States of California and Massachusetts.

The EPA recognizes that changes in perchlorate levels (increasing or decreasing) may have occurred in water systems since the UCMR 1 samples were collected between 2001 to 2005. The EPA updated the UCMR 1 data set to improve its accuracy in representing the current conditions for states that have enacted perchlorate regulations since the UCMR 1 monitoring was conducted. As outlined in the June 26, 2019 proposal, the EPA updated occurrence data for California and Massachusetts with current compliance data as reported by the states. Systems from these two states that were sampled during the UCMR 1 and that had reported perchlorate detections were updated with more recently measured values taken from current compliance monitoring data from Consumer Confidence Reports and state-level perchlorate compliance monitoring data to match corresponding water systems and entry points.

The EPA has determined that the updated UCMR 1 data are the best available data collected in accordance with accepted methods on the frequency and level of perchlorate occurrence in drinking water on a national scale.

V. Conclusion

With this withdrawal of the 2011 perchlorate regulatory determination and final determination to not regulate perchlorate, the EPA announces that there will be no NPDWR for perchlorate at this time. The EPA could consider re-listing perchlorate on the CCL and could proceed to regulation in the future if the occurrence or health risk information changes. As with other unregulated contaminants, the EPA will consider addressing limited instances of elevated levels of perchlorate by working with the affected system and state, as appropriate.

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List of Subjects in 40 CFR Parts 141 and 142

Administrative practice and procedure, Chemicals, Indians-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated:____________________

____

Andrew Wheeler,

Administrator.

*** Deliberative Draft – Do Not Cite, Quote, or Release During Review***

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[EPA-HQ-OW-2018-0780, EPA–HQ–OW–2008–0692, EPA–HQ–OW– 2009–0297; FRL-XXXX-XX-OW]

RIN 2040-AF28

Drinking Water: Notice of ~~Withdrawal of the 2011 Perchlorate Regulatory Determination and Publication of the~~ **Final** Action~~Regulatory Determination~~ **on Perchlorate**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of Regulatory Determination and Final Regulatory Determination.

SUMMARY: The Environmental Protection Agency (EPA) is announcing its withdrawal of the 2011 determination to regulate perchlorate in accordance with the Safe Drinking Water Act (SDWA). On February 11, 2011 ~~(76 FR 7762)~~, the ~~Agency~~EPA published a *Federal Register* notice in which the ~~EPA~~Agency determined that perchlorate met the SDWA's criteria for regulating a contaminant. On June 26, 2019 ~~(84 FR 30524)~~, the EPA published a proposed national primary drinking water regulation (NPDWR) for perchlorate and requested public comments on multiple alternative regulatory actions, including the alternative of withdrawing the 2011 regulatory determination for perchlorate. The ~~Agency~~EPA received approximately 1,500 comments on the proposed rule. The EPA has considered these public comments and based on the best available information the Agency is withdrawing the 2011 regulatory determination and

is making a final determination to not ~~to~~ regulate perchlorate. The ~~Agency~~EPA has determined that perchlorate does not occur with a frequency and at levels of public health concern, and that regulation of perchlorate does not present a meaningful opportunity for health risk reduction for persons served by public water systems.

DATES: For purposes of judicial review, the regulatory determination in this document is issued as of *[insert date of publication in the* Federal Register*]***.**

FOR FURTHER INFORMATION CONTACT: Samuel Hernandez, Office of Ground Water and Drinking Water, Standards and Risk Management Division (Mail Code 4607M), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone number: (202) 564-1735; email address: hernandez.samuel@epa.gov.

SUPPLEMENTARY INFORMATION: This notice is organized as follows:

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I. General Information

A. Does This Action Apply to Me?

This action will not impose any requirements on anyone. Instead, this action notifies interested parties of the EPA's withdrawal of the 2011 regulatory determination for perchlorate and the final regulatory determination to not regulate perchlorate ~~based on new information.~~.

This notice also provides a summary of the major comments received on the June 26, 2019 (84 FR 30524) proposed NPDWR for perchlorate.

B. How can I get Copies of this Document and other Related Information?

The EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2018–0780. Publicly available docket materials are available electronically at [HYPERLINK "http://www.regulations.gov/docket?D=EPA-HQ-OW-2018-0780"].

II. Background

A. What is Perchlorate?

Perchlorate is a negatively charged inorganic ion that is comprised of one chlorine atom bound to four oxygen atoms (ClO_4-), which is highly stable and mobile in the aqueous environment. Perchlorate comes from both natural and manmade sources. It is formed naturally via atmospheric processes and can be found within mineral deposits in certain geographical areas. It is also produced in the United States, and the most common compounds include ammonium perchlorate and potassium perchlorate used primarily as oxidizers in solid fuels to power rockets, missiles, and fireworks. Perchlorate can also result from the degradation of hypochlorite solutions used for water disinfection. The degradation into perchlorate occurs when hypochlorite solutions are improperly stored and handled. For the general population, most perchlorate exposure is through the ingestion of contaminated food or drinking water. At certain levels, perchlorate can prevent the thyroid gland from getting enough iodine, which can affect thyroid hormone production. For pregnant women with low iodine levels, sufficient changes in thyroid hormone levels may cause changes in the child's brain development. For infants, changes to thyroid hormone function can also impact brain development.

B. What is the purpose of this action?

The purpose of ~~today's~~this action is to publish the EPA's notice to withdraw the 2011 regulatory determination and issue a final determination to not regulate perchlorate in drinking water. This notice presents the EPA's basis for this withdrawal and final regulatory determination, and the EPA's response to key issues raised by commenters in response to the June 26, 2019 (84 FR 30524) proposed rule (referred to hereinafter as "the 2019 proposal").

C. What is the EPA's statutory authority for this action?

The SDWA sets forth three criteria that must be met for the EPA to issue a maximum contaminant level goal (MCLG) and promulgate a national primary drinking water regulation (NPDWR). Specifically, the Administrator must determine that (1) "the contaminant may have an adverse effect on the health of persons"; (2) "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern"; and (3) "in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by ~~the~~ public water systems" (SDWA 1412(b)(1)(A)).

The EPA has determined, based on ~~new~~ data and analysis since the issuance of the 2011 regulatory determination, that perchlorate does not in fact meet the statutorily-prescribed criteria for regulation. As described in Sections III & VI of the 2019 proposal, the ~~new~~ data and analysis in the record indicate that perchlorate does not occur in public water systems with a frequency and at levels of public health concern. Specifically, the ~~new~~ peer-reviewed health effects analysis ~~yields a health-based proposed MCLG and proposed alternative MCLGs for~~ indicates that the concentration of perchlorate ~~that are higher concentrations in drinking water (18 – 90 μg/L) than the concentrations that the EPA considered to be~~representing levels of public health concern ~~in~~(18-90 μg/L) is higher than the concentration considered in issuance of the ~~analysis for the~~ 2011 regulatory determination ~~to regulate in 2011~~ (1-47 μg/L) (USEPA, 2019a). In addition, based on an evaluation of the nationally representative UCMR 1 systems, the updated occurrence analysis shows that the frequency of occurrence of perchlorate in public water systems at levels exceeding any of the alternative proposed MCLGs ~~(0.38% – 0.02%)~~ is significantly lower (0.38% - 0.02%) than the frequency considered in the analysis for the 2011 regulatory determination (4% - 0.39%) (USEPA, 2019b). The EPA estimates that, even at the most stringent regulatory level considered in the 2019 proposal~~,~~ (18 μg/L), not more than 15 systems (0.03% of all water systems in the U.S.) would need to take action to reduce levels of perchlorate. Based on this information, the EPA determines that perchlorate does not occur in public water systems "with a frequency…of public health concern" and thus does not meet the second criterion of the three required for regulation under the SDWA. In addition, while the third criterion is "in the sole judgement of the Administrator," the low occurrence provides ample support for the EPA's conclusion that the regulation of perchlorate does not present a "meaningful opportunity for health risk reduction for persons served by public water systems," within the meaning of 1412(b)(1)(A)(iii). Accordingly, because perchlorate no longer meets the statutory criteria for regulation, the EPA does not have the authority to issue a MCLG or promulgate a NPDWR for perchlorate.

The EPA's decision to withdraw the regulatory determination is supported by the legislative history underlying the 1996 amendments to the SDWA, which repealed the ~~blanket rule requiring~~statutory requirement for the EPA to regulate an additional 25 contaminants every 3 years and replaced it with the current requirement for the EPA to determine whether regulation is warranted for ~~5~~five contaminants every ~~5~~five years. In describing the need for such amendment, the legislative history points to the view expressed at the Committee Hearing that "the current law is a one-size-fits-all program. It forces our water quality experts to spend scarce resources searching for dangers that often do not exist rather than identifying and removing real health risks from our drinking water" (S. Rep. 104-169 (1995) at 12). This amendment reflected Congress' clear intent that the EPA prioritize actual health risks in determining whether to regulate any particular contaminant. *See id* at 12 (noting that the amendment "repeals the requirement that the EPA regulate an additional 25 contaminants every 3 years replacing it with a new selection process that gives the EPA the discretion to identify contaminants that warrant regulation in the future").

The EPA's decision to withdraw the regulatory determination is also consistent with Congress' direction to prioritize the SDWA decisions based on the best available public health information. *See* 1412(b)(1)(B)(ii)(II) (findings supporting a determination to regulate "shall be based on the best available public health information"); 1412(b)(2)(A) (requiring that the EPA use "the best available, peer-reviewed science and supporting studies…" in carrying out any actions under this section). Although the EPA determined in 2011 that perchlorate met the criteria for regulation, new data and analysis developed by the ~~EPA~~Agency as part of the 2019 proposal demonstrate that the occurrence and health effects information used as the basis for the 2011 determination no longer constitute "best available information," are no longer accurate and no longer support the Agency's prioritization of perchlorate for regulation. Accordingly, not only is EPA not authorized to issue a MCLG or promulgate a NPDWR for perchlorate, but it would not be in the public interest to do so.

The EPA recognizes that the Act does not include a provision explicitly authorizing withdrawal of a regulatory determination. However, such authority is inherent in the authority to issue a regulatory determination under 1412(b)(1)(B)(ii)(II), particularly given the requirement that such determination be based on the "best available public health information," as discussed above. Accordingly, the EPA must have the inherent authority to withdraw a regulatory determination if the underlying information changes between regulatory determination and promulgation. ~~Particularly~~ In light of its concern that the EPA focus new contaminant ~~regulation~~regulations on priority health concerns, Congress could not have intended that the EPA's regulatory decision-making be hamstrung by older data when newer, more accurate scientific and public health data are available, especially when those data demonstrate that regulation of a new contaminant would not ~~be~~present a meaningful opportunity for health risk reduction.

Moreover, the EPA notes that the statute specifically provides that a decision to not ~~to~~ regulate a contaminant is a final Agency action subject to judicial review. The SDWA, section 1412(b)(1)(B)(ii)(IV). ~~Congress'~~Congress could have – but did not – specify the same with respect to determinations to regulate. Congress also did not explicitly prohibit the EPA from withdrawing or modifying a regulatory determination. Congress' silence with respect to ~~regulatory~~ determinations to regulate suggests that Congress intended that such ~~determinations are~~a determination is not ~~in fact~~itself a final agency ~~actions subject to judicial review~~action, but rather, a preliminary ~~decisions to regulate~~step in a decision-making process culminating in a NPDWR and thus, subject to reconsideration based on new data and analysis considered during the 36 month promulgation process specified in the statute. Accordingly, reconsideration of this preliminary finding – and withdrawal of the determination based on subsequent analysis mandated for NPDWR development – is fully consistent with the statutory decision-making framework.

D. Statutory Framework and Perchlorate Regulatory History

Section 1412(b)(1)(B)(i) of the SDWA requires the EPA to publish every five years a Contaminant Candidate List (CCL). The CCL is a list of drinking water contaminants that are known or anticipated to occur in public water systems and are not currently subject to federal drinking water regulations. The EPA uses the CCL to identify priority contaminants for regulatory decision-making and information collection. Contaminants listed on the CCL may require future regulation under the SDWA. The EPA included perchlorate on the first, second, and third CCLs published in 1998 (63 FR 10274), 2005 (70 FR 9071), and 2009 (74 FR 51850).

The ~~Agency~~ EPA collects data on the CCL contaminants to better understand their potential health effects and to determine the levels at which they occur in public water systems. The SDWA, section 1412(b)(1)(B)(ii) requires that, every five years, the EPA, after consideration of public comment, issue a determination of whether or not to regulate at least five contaminants on each CCL. For any contaminant that the EPA determines meets the SDWA criteria for regulation, under the SDWA, section 1412(b)(1)(E), the EPA must propose a NPDWR within two years and promulgate a final regulation within 18 months of the proposal (which may be extended by 9 additional months).

As part of its responsibilities under the SDWA, the EPA implements section 1445(a)(2), "Monitoring Program for Unregulated Contaminants." This section requires that once every five years, the EPA issue a list of no more than 30 unregulated contaminants to be monitored by public water systems. This monitoring is implemented through the Unregulated Contaminant Monitoring Rule (UCMR), which collects data from community water systems ~~(CWS)~~ and non-transient, non-community water systems ~~(NTNCWS)~~. The first four UCMRs collected data from a census of large water systems (serving more than 10,000 people) and from a statistically representative sample of small water systems. On September 17, 1999, the EPA published its first UCMR (64 FR 50556)~~)~~, which required all large systems and a representative sample of small systems to monitor for perchlorate and 25 other contaminants (USEPA, 1999). Water system monitoring data for perchlorate was collected from 2001 to 2005.

The EPA and other federal agencies asked the National Research Council (NRC) to evaluate the health implications of perchlorate ingestion. In its 2005 report, the NRC concluded that perchlorate exposure inhibits the transport of iodide[1] into the thyroid by a protein molecule known as the sodium/iodide symporter (NIS), which may lead to decreases in two thyroid hormones, thyroxine (T3) and triiodothyronine (T4), and increases in thyroid-stimulating hormone (TSH) [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a1mn5hjprkt","properties":{"formattedCitation":"(National Research Council (NRC), 2005b)","plainCitation":"(National Research Council (NRC), 2005b)","noteIndex":0},"citationItems":[{"id":350,"uris":["http://zotero.org/groups/945096/items/TN6HMC9D"],"uri":["http://zotero.org/groups/945096/items/TN6HMC9D"],"itemData":{"id":350,"type":"book","title":"Health Implications of Perchlorate Ingestion","publisher":"National Academies Press","publisher-place":"Washington, DC","event-place":"Washington, DC","author":[{"literal":"National Research Council (NRC)"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Additionally, the NRC concluded that the

[1] For the purposes of this notice, "iodine" will be used to refer to dietary intake before entering the body. Once in the body, "iodide" will be used to refer to the ionic form.

most sensitive population to perchlorate exposure are "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" (p. 178). The EPA established a reference dose (RfD) consistent with the NRC's recommended RfD of 0.7 μg/kg/day for perchlorate. The reference dose is an estimate of a human's daily exposure to perchlorate that is likely to be without an appreciable risk of adverse effects. This RfD was based on a study [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a3u94lt6me","properties":{"formattedCitation":"(Greer, Goodman, Pleus, & Greer, 2002)","plainCitation":"(Greer, Goodman, Pleus, & Greer, 2002)","noteIndex":0},"citationItems":[{"id":387,"uris":["http://zotero.org/groups/945096/items/6AKUNIX6"],"uri":["http://zotero.org/groups/945096/items/6AKUNIX6"],"itemData":{"id":387,"type":"article-journal","title":"Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans","container-title":"Environmental Health Perspectives","page":"927","volume":"110","issue":"9","author":[{"family":"Greer","given":"Monte A."},{"family":"Goodman","given":"Gay"},{"family":"Pleus","given":"Richard C."},{"family":"Greer","given":"Susan E."}],"issued":{"date-parts":[["2002"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] of perchlorate's inhibition of radioactive iodine uptake in healthy adults and the application of an uncertainty factor of 10 for intraspecies variability [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"0oHz805e","properties":{"formattedCitation":"(USEPA, 2005b)","plainCitation":"(USEPA, 2005b)","noteIndex":0},"citationItems":[{"id":980,"uris":["http://zotero.org/groups/945096/items/LHANJBR6"],"uri":["http://zotero.org/groups/945096/items/LHANJBR6"],"itemData":{"id":980,"type":"article","title":"Integrated Risk Information System (IRIS) Chemical Assessment Summary: Perchlorate (ClO4-) and Perchlorate Salts","publisher":"USEPA National Center for Environmental Assessment","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

In October 2008, the EPA published a preliminary regulatory determination to not ~~to~~ regulate perchlorate in drinking water and requested public comment (73 FR 60262). In that preliminary determination, the EPA found that perchlorate did not occur with a frequency and at levels of public health concern and that development of a regulation did not present a meaningful opportunity for health risk reduction for persons served by public water systems. The EPA derived and used a Health Reference Level (HRL) of 15 µg/L based on the RfD of 0.7 µg/kg/day and body weight and exposure information for pregnant women in making this conclusion [ADDIN ZOTERO_ITEM CSL_CITATION

{"citationID":"FZ6WMtAv","properties":{"formattedCitation":"(USEPA, 2008a)","plainCitation":"(USEPA, 2008a)","noteIndex":0},"citationItems":[{"id":934,"uris":["http://zotero.org/groups/945096/items/HBX88QM9"],"uri":["http://zotero.org/groups/945096/items/HBX88QM9"],"itemData":{"id":

934,"type":"article-journal","title":"Drinking water: Preliminary regulatory determination on perchlorate","container-title":"Federal Register","volume":"73","issue":"198","abstract":"SUMMARY: This action presents EPA's preliminary regulatory determination for perchlorate in accordance with the Safe Drinking Water Act (SDWA). The Agency has determined that a national primary drinking water regulation (NPDWR) for perchlorate would not present \"a meaningful opportunity for health risk reduction for persons served by public water systems." The SDWA requires EPA to make determinations every five years of whether to regulate at least five contaminants on the Contaminant Candidate List (CCL). EPA included perchlorate on the first and second CCLs that were published in the Federal Register on March 2, 1998 and February 24, 2005. Most recently, EPA presented final regulatory determinations regarding 11 contaminants on the second CCL in a notice published in the Federal Register on July 30, 2008. In today's action, EPA presents supporting rationale and requests public comment on its preliminary regulatory determination for perchlorate. EPA will make a final regulatory determination for perchlorate after considering comments and information provided in the 30-day comment period following this notice. EPA plans to publish a health advisory for perchlorate at the time the Agency publishes its final regulatory determination to provide State and local public health officials with technical information that they may use in addressing local contamination.","ISSN":"ISSN 0097-6326 EISSN 2167-2520","shortTitle":"Federal Register","journalAbbreviation":"Fed. Reg.","language":"English","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2008"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Using the UCMR 1 occurrence data, the EPA estimated that less than 1% of drinking water systems (serving approximately 1 million people) had perchlorate levels above the HRL of 15 µg/L. Based on this information the ~~Agency~~EPA found that perchlorate did not occur ~~frequently~~at a frequency and at levels of public health concern. The EPA also determined there was not a meaningful opportunity for a NPDWR for perchlorate to reduce health risks.

In August 2009, the EPA published a supplemental request for comment with new analysis that derived potential alternative Health Reference Levels (HRLs) for 14 life stages, including infants and children. The analysis used the RfD of 0.7 µg/kg/day and life stage-specific bodyweight and exposure information, resulting in comparable perchlorate concentrations in drinking water, based on life stage, of between 1 µg/l to 47 µg/l (74 FR 41883; USEPA, 2009).

~~On~~In February 11, 2011, the EPA published its determination to regulate perchlorate (76 FR 7762; USEPA, 2011) after careful consideration of public comments on the October 2008 and August 2009 notices. The ~~Agency~~EPA found at that time that perchlorate may have an adverse effect on the health of persons, it is known to occur in public drinking water systems with a frequency and at levels that present a public health concern, and regulation of perchlorate presented a meaningful opportunity for health risk reduction for persons served by public water systems. The ~~Agency~~EPA stated then that: "*Based on the data in Table 1 and the range of potential alternative HRLs, EPA has determined that perchlorate is known to occur or there is a* *substantial likelihood that it will occur with a frequency and at levels of public health concern.*"(USEPA, 2011, p. 7765). The EPA found that as many as 16 million people could potentially be exposed to perchlorate at levels of concern, up from 1 million people originally estimated in the 2008 notice.

As a result of the determination, and as required by the SDWA, section 1412(b)(1)(E), the EPA initiated the process to develop a MCLG and a NPDWR for perchlorate.

In September 2012, the U.S. Chamber of Commerce (the Chamber) submitted to the EPA a Request for Correction under the Information Quality Act regarding the EPA's regulatory determination. In the request, the Chamber claimed that the UCMR 1 data used in the EPA's occurrence analysis did not comply with data quality guidelines and were not representative of current conditions. In response to this request, the EPA reassessed the data and removed certain source water samples that could be paired with appropriate follow-up samples located at the entry point to the distribution system. The EPA also updated the UCMR 1 data in the analysis for systems in California and Massachusetts, using state compliance data to reflect current occurrence conditions after state regulatory limits for perchlorate were implemented.

As required by section 1412(d) of the SDWA, as part of the NPDWR development process, the EPA requested comments from the Science Advisory Board (SAB) in 2012, seeking guidance on how best to consider and interpret the life stage information, the epidemiologic and biomonitoring data since the NRC report, physiologically-based pharmacokinetic (PBPK) analyses, and the totality of perchlorate health information to derive an MCLG for perchlorate. In May 2013, the SAB recommended that the EPA:

- derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling based upon its mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters;
- expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;
- utilize a mode-of-action framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition—to thyroid hormone changes—and finally to neurodevelopmental impacts; and
- ''Extend the [BBDR] model expeditiously to . . . provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages''(SAB for the U.S. EPA, 2013, p. 19).

To address the SAB recommendations, the EPA revised an existing PBPK/PD model that describes the dynamics of perchlorate, iodide, and thyroid hormones in a woman during the third trimester of pregnancy (Lumen, Mattie, & Fisher, 2013; USEPA, 2009b). The EPA also created its own Biologically Based Dose Response (BBDR) models that included the additional sensitive life stages identified by the SAB, *i.e.*, breast- and bottle-fed neonates and infants (SAB for the U.S. EPA, 2013, p. 19).

To determine whether the Agency had implemented the SAB recommendations for modeling thyroid hormone changes, the EPA convened an independent peer review panel to evaluate the BBDR models in January 2017 (External Peer Reviewers for USEPA, 2017). The EPA considered the recommendations from the 2017 peer review and made necessary model revisions to increase the scientific rigor of the model and the modeling results.

The EPA convened a second independent peer review panel in January 2018 to evaluate the revisions to the BBDR model. The EPA also presented several approaches to link the thyroid hormone changes in a pregnant mother predicted by the BBDR model to neurodevelopmental effects using evidence from the epidemiological literature (External Peer Review for U.S. EPA, 2018).

In response to a lawsuit brought to enforce the deadlines in the SDWA, section 1412(b)(1)(E), on October 18, 2016, the U.S. District Court for the Southern District of New York entered a consent decree, requiring the EPA to sign for publication a proposal for a MCLG and NPDWR for perchlorate in drinking water no later than October 31, 2018, and to sign for publication a final MCLG and NPDWR for perchlorate in drinking water no later than December 19, 2019. The deadline for the EPA to propose a MCLG and NPDWR for perchlorate in drinking water was later extended to May 28, 2019, and the date for signature of a final MCLG and

NPDWR was extended to be no later than June 19, 2020. The consent decree is available in the docket for ~~today's~~this action.

In compliance with the deadline established in the consent decree, on May 23, 2019, the EPA Administrator signed a proposed rulemaking notice seeking public comment on a range of options regarding the regulation of perchlorate in public drinking water systems. The proposed rulemaking notice was published in the *Federal Register* on June 26, 2019. 84 Fed. Reg. 30524. The EPA proposed a NPDWR for perchlorate with ~~a~~an MCL and MCLG of 56 µg/L. The proposed MCLG of 56 µg/L was based on avoiding a 2 point IQ decrement associated with exposure to perchlorate in drinking water during the most sensitive life stage (the fetus) within a specific segment of the population (iodine deficient pregnant women).

The ~~Agency~~EPA also requested comment on two alternative MCL/MCLG values of 18 µg/L and 90 µg/L~~, respectively.~~. These alternatives were based upon avoiding 1 point and 3 point IQ decrements respectively, associated with perchlorate exposure. Additionally, the EPA requested comment on whether the 2011 regulatory determination should be withdrawn, based on new information including updated occurrence data on perchlorate in drinking water and new analysis of the concentration of perchlorate in drinking water that represents a level of health concern.

III. Withdrawal of the 2011 Regulatory Determination and Final Determination to Not Regulate Perchlorate

In determining whether to regulate a particular contaminant, the EPA must follow the criteria mandated by the 1996 SDWA Amendments. Specifically, in order to issue a MCLG and NPDWR for perchlorate, the EPA must determine that perchlorate "may have an adverse effect on the health of persons," that perchlorate occurs at "a frequency and at levels of public health concern" in public water systems, and that regulation of perchlorate in drinking water systems "presents a meaningful opportunity for health risk ~~reductions~~reduction for persons served by public water systems." The SDWA, section 1412(b)(1)(A). In preparing the 2019 proposal for perchlorate, the EPA updated and improved information on the levels of public health concern and the frequency and levels of perchlorate in public water systems. The following is the EPA's reassessment of the regulatory determination criteria applied to the ~~improved~~best available health science and occurrence data ~~available~~ for perchlorate.

A. May perchlorate have an adverse effect on the health of persons?

Yes, perchlorate may have adverse health effects. The perchlorate anion is biologically significant specifically with respect to the functioning of the thyroid gland. Perchlorate can interfere with the normal functioning of the thyroid gland by inhibiting the transport of iodide into the thyroid, resulting in a deficiency of iodide in the thyroid. Perchlorate inhibits (or blocks) iodide transport into the thyroid by chemically competing with iodide, which has a similar shape and electric charge. The transfer of iodide from the blood into the thyroid is an essential step in the synthesis of thyroid hormones. Thyroid hormones play an important role in the regulation of metabolic processes throughout the body and are also critical to developing fetuses and infants, especially for brain development. Because the developing fetus depends on an adequate supply of maternal thyroid hormones for its central nervous system development during the first and second trimester of pregnancy, iodide uptake inhibition from perchlorate exposure has been identified as a concern in connection with increasing risk of neurodevelopmental impairment in fetuses of pregnant women with low dietary iodine. Poor iodide uptake and subsequent impairment of the thyroid function in pregnant and lactating women have been linked to delayed development and decreased learning capability in their infants and children (NRC, 2005). Therefore, the EPA continues to find that perchlorate may have an adverse effect on the health of persons.

B. Is perchlorate known to occur or is there a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern?

The EPA has determined that perchlorate does not occur ~~at~~with a frequency and at levels of public health concern in public water systems. The EPA has made this determination by comparing the best available data on the occurrence of perchlorate in public water systems to potential MCLGs for perchlorate.

In past regulatory determinations, the EPA has identified HRLs as benchmarks against which the EPA compares the concentration of a contaminant found in public water systems to determine if it ~~is~~occurs at levels of public health concern. For the 2011 regulatory determination the EPA identified potential HRLs values ranging from 1 to 47 µg/L for 14 different life-stages.

These HRLs were not final decisions about the level of perchlorate in drinking water that is ~~necessary to protect any particular population~~ without adverse effects. For the 2019 proposal, the EPA derived three potential MCLGs for perchlorate of 18, 56, and 90 µg/L for the most sensitive life- stage ~~utilizing~~using the best available peer reviewed science in accordance with the SDWA. ~~The proposed~~After considering public comment, the EPA used these potential MCLGs ~~are~~as the levels of public health concern ~~used~~in assessing the frequency of occurrence of perchlorate in this regulatory determination. These MCLGs were set at levels to avoid IQ decrements of 1, 2, and 3 points respectively in the most sensitive life stage, the children of hypothyroxinemic women with low iodine intake. The EPA proposed an MCLG of 56 µg/L~~.~~ and alternative MCLG values of 18 and 90 µg/L.

The rationale used in deriving the numerical values is presented in greater detail in the EPA's technical support document titled "Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (USEPA, 2019b).

The EPA compared these potential MCLG values to the updated perchlorate UCMR 1 occurrence data set. A comprehensive description of the perchlorate occurrence data is presented in Section VI of the 2019 proposal. It is also available in the "Perchlorate Occurrence and Monitoring Report" (USEPA, 2019a).

The occurrence data for perchlorate ~~was~~were collected from 3,865 PWSs between 2001 and 2005 under the UCMR 1. ~~The Agency has~~In the 2019 proposal, the EPA modified ~~its~~the UCMR 1 data set in response to concerns raised by stakeholders regarding the data quality and to represent current conditions in California and Massachusetts, which have enacted perchlorate regulations since the UCMR 1 data ~~was~~were collected. Massachusetts promulgated a drinking water standard for perchlorate of 2 μg/L in 2006 [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"8DPpSrv3","properties":{"formattedCitation":"(MassDEP, 2006)","plainCitation":"(MassDEP, 2006)","noteIndex":0},"citationItems":[{"id":151,"uris":["http://zotero.org/groups/945096/items/9893MBZH"],"uri":["http://zotero.org/groups/945096/items/9893MBZH"],"itemData":{"id":151,"type":"personal_communication","title":"Letter to Public Water Suppliers concerning new perchlorate regulations","URL":"https://www.mass.gov/lists/perchlorate-background-information-and-standards#perchlorate---final-standards-","author":[{"literal":"MassDEP"}],"issued":{"date-parts":[["2006"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], and California promulgated a drinking water standard of 6 μg/L in 2007 [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"cfr6HNhg","properties":{"formattedCitation":"(California Department of Public Health, 2007)","plainCitation":"(California Department of Public Health, 2007)","noteIndex":0},"citationItems":[{"id":150,"uris":["http://zotero.org/groups/945096/items/RA45NKLQ"],"uri":["http://zotero.org/groups/945096/items/RA45NKLQ"],"itemData":{"id":150,"type":"personal_communication","title":"State Adoption of a Perchlorate Standard","URL":"https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/docum ents/perchlorate/AdoptionMemotoWaterSystems-10-2007.pdf","author":[{"literal":"California Department of Public Health"}],"issued":{"date-parts":[["2007"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Systems in these states are now required to keep perchlorate levels in drinking water below their state limits. As discussed below, the EPA finds that perchlorate levels in drinking water and sources of drinking water have decreased since the ~~UCMR1~~UCMR 1 data collection. The main factors contributing to the decrease in perchlorate levels are the promulgation of drinking water regulations for perchlorate in California and Massachusetts and the ongoing remediation efforts in the state of Nevada to address perchlorate contamination in groundwater adjacent to the lower Colorado River upstream of Lake Mead.

To update the occurrence data for systems sampled during UCMR 1 from California and Massachusetts, the EPA identified all systems and corresponding entry points which had reported perchlorate detections in UCMR 1. Once the systems and entry points with detections were appropriately identified, the EPA then used a combination of available data from Consumer Confidence Reports (CCRs) and perchlorate compliance monitoring data from California (https://sdwis.waterboards.ca.gov/PDWW/) and Massachusetts (https://www.mass.gov/service-details/public-water-supplier-document-search) to match current compliance monitoring data (where available) to the corresponding water systems and entry points sampled during UCMR 1.

~~With these updates,~~ The EPA has determined that the UCMR 1 data with these updates are the best available data collected in accordance with accepted methods regarding the frequency and level of perchlorate nationally. The UCMR 1 data are from a census of the large water systems (serving more than 10,000 people) and a statistically representative sample of small water systems that provides the best available, national assessment of perchlorate occurrence in drinking water.

The EPA used entry point maximum measurements to estimate potential baseline occurrence and exposure at levels that exceed the potential MCLG thresholds. The maximum measurements indicate highest perchlorate levels reported in at least one quarterly sample from surface water systems and at least one semi-annual sample from ground water systems.

Table 1: Perchlorate Occurrence and Exposure (Updated UCMR 1 Data Set)

Threshold Concentration (µg/L)	Entry Points with Detections above Threshold	Water Systems with Detections above Threshold	Percent of U.S. Water Systems with Detections above Threshold	Population Served
18 µg/L	17	15	0.03 %	620,560
56 µg/L	2	2	0.004 %	32,432
90 µg/L	1	1	0.002 %	25,972

Table 1 presents the number and percentage of water systems that reported perchlorate at levels exceeding the three proposed MCLG threshold concentrations. In summary, the updated perchlorate occurrence information suggests that at an MCLG of 18 µg/L, there would be 15 systems (0.03% of all water systems in the U.S.) that would exceed the threshold, at an MCLG of 56 µg/L, two systems (0.004% of all water systems in the U.S.) would exceed the threshold, and finally one system would exceed the MCLG threshold of 90 µg/L. Based on the analysis of drinking water occurrence presented in the 2019 proposal and the data summarized in Table 1 and the range of potential MCLGs, the EPA concludes that perchlorate does not occur ~~at~~with a frequency and at levels of public health concern in public water systems.

While the EPA has made its conclusion that perchlorate ~~occurs infrequently~~does not occur at a frequency and at levels of public health concern in public water systems based on the updated UCMR 1 data, the EPA also sought to find additional information about the perchlorate levels at the 15 water systems that had at least one reported result greater than 18 µg/L in the updated UCMR 1 data. The EPA found that perchlorate levels have been reduced at many of these water systems. Although these water systems were not required to take actions to reduce perchlorate in drinking water, many had conducted additional monitoring for perchlorate and found decreased levels or had taken mitigation efforts to address perchlorate, confirming the EPA's conclusion described above. The status of each of these systems is described in Table 2 below.

Table 2: Update on Systems with Perchlorate levels above 18 µg/L in the UCMR 1

State	**System Name**	**Range of UCMR 1 Results (µg/L)****	**Update on Mitigation and Levels of Perchlorate**++
Florida	Sebring Water	ND-70	The EPA contacted the Sebring system in January 2020. Operations personnel indicated that no follow-up/updated monitoring data for perchlorate are available.

State	System Name	Range of UCMR 1 Results (µg/L)**	Update on Mitigation and Levels of Perchlorate++
Florida	Manatee County Utilities Dept	ND-30	Researchers contacted the system to identify the source of perchlorate. System personnel attributed the sole perchlorate detection under ~~UCMR1~~UCMR 1 to analytical error. System personnel indicated that three other quarterly samples collected under ~~UCMR1~~UCMR 1 as well as other subsequent perchlorate sampling efforts were non-detect. Source: AWWA (2008)
Georgia	Oconee Co.-Watkinsville	38 (single sample)	Researchers contacted the system and found that a perchlorate contaminated well was removed from service in 2003. The system indicates that perchlorate is no longer detected. Source: Luis et al. (2019)
Louisiana	St. Charles Water District 1 East Bank	ND-24	The EPA was not able to identify updated data on perchlorate levels for this system.
Maryland	City of Aberdeen	ND-19	The system's 2018 Consumer Confidence Report (CCR) indicates that perchlorate was not detected. According to the Maryland Department of Environment, perchlorate was not detected in this system in 2019. In addition, researchers contacted the system and found that there has been no detection of perchlorate since treatment was installed in 2009. Source: Luis et al. (2019)
Maryland	Chapel Hill - Aberdeen Proving Grounds	ND-20	The EPA contacted the Chapel Hill System in January 2020. Water system personnel indicate that the Chapel Hill WTP was taken off-line and was replaced with a new treatment plant and five new production wells. The new treatment plant started operations on January 27, 2020. System personnel also indicate that monitoring was conducted in November 2019 and perchlorate was not detected in either the source well water or the finished water. In

State	System Name	Range of UCMR 1 Results (µg/L)**	Update on Mitigation and Levels of Perchlorate++
			addition, according to the Maryland Department of Environment, perchlorate was not detected in this system in 2019.
Mississippi	Hilldale Water District	ND-20	The EPA contacted the Hilldale System in January 2020. Water system personnel indicated that no follow-up/updated monitoring data for perchlorate are available.
New Mexico	Deming Municipal Water System	15-20	Data from the EPA's SDWIS/FED database indicates that the entry point that reported detections in ~~UCMR1~~UCMR 1 (Well #3) is now inactive (i.e., the contaminated source is no longer in use). ~~Source: SDWIS/FED (2016).~~
Nevada	City of Henderson	6-23	Researchers report that the perchlorate levels described in the system's CCR ranged from non-detect to 9.7 µg/L. Source AWWA (2008).
Ohio	Fairfield City PWS	6-27	The EPA contacted the Fairfield City System in January 2020. Water system personnel indicated that follow-up monitoring was conducted after ~~UCMR1~~UCMR 1, between 2002 and 2004. The Ohio EPA provided copies of the follow-up monitoring results which indicate that results at the entry point ranged from non-detect to 13 µg/L.
Ohio	Hecla Water Association-Plant PWS	ND-32	The EPA contacted the Hecla Water Association System in January 2020. Water system personnel indicated that that no follow-up/updated monitoring data for perchlorate are available.
Oklahoma	Enid	ND-30	The EPA reviewed Oklahoma's monitoring data and did not find any monitoring results reported for perchlorate.
Pennsylvania	Meadville Area Water Authority	ND-33	The EPA contacted the Meadville System in January 2020. Water system personnel indicated that no

State	System Name	Range of UCMR 1 Results (µg/L)**	Update on Mitigation and Levels of Perchlorate++
			follow-up/updated monitoring data for perchlorate are available.
Puerto Rico	Utuado Urbano	ND-420	The EPA contacted the Puerto Rico Aqueduct and Sewer Authority (PRASA) in January 2019. PRASA personnel indicated that no updated monitoring data for perchlorate are available. *NOTE: The PRASA personnel stated that the Utuado water system was significantly impacted by hurricane Maria and monitoring records from years prior to 2017 were lost.*
Texas	City of Levelland	ND-32	Researchers found that a water storage tank was the source of perchlorate contamination, the wells feeding the tank were tested by the state and perchlorate was not detected. The water tank was shut off from service. Source: Luis et al. (2019).

** - Values have been rounded. ND describes a sampling event where perchlorate was not detected at or above the UCMR 1 minimum reporting level of 4 µg/L. UCMR 1 results collected between 2001 and 2005.

++ - To obtain updated data and/or information regarding perchlorate levels, the EPA reviewed Consumer Confidence Reports and other publicly available data, as well as published studies. In addition, the EPA contacted some water systems for information about current perchlorate levels. (USEPA, 2020b)

C. Is there a meaningful opportunity for the reduction of health risks from perchlorate for persons served by public water systems?

The ~~Agency's~~EPA's analysis presented in the 2019 proposal demonstrates that a NPDWR for perchlorate does not present a meaningful opportunity for health risk reduction for persons served by public water systems. As discussed above, the EPA found that perchlorate occurs with very low frequency at levels of public health concern. Based on updated UCMR 1 occurrence information, there were 15 water systems (0.03% of all water systems in the U.S.) that detected perchlorate in drinking water above the lowest proposed alternative MCLG of 18 µg/L and only 1 system had a detection above the proposed alternative MCLG of 90 µg/L. Specifically, Table 1 presents the population served by PWSs that were monitored under UCMR 1 for which the highest reported perchlorate concentration was greater than the identified thresholds. The EPA estimates[2] that the number of people who may be potentially consuming water containing perchlorate at levels that could exceed the levels of concern for perchlorate could range between 26,000 toand 620,000. The small number of water systems with perchlorate levels greater than identified thresholds and the corresponding small population served provides ample support for the EPA's conclusion that the regulation of perchlorate does not present a "meaningful opportunity for health risk reduction for persons served by public water systems," within the meaning of the SDWA, section 1412(b)(1)(A)(iii).

The EPA also considered the findings of the Health Risk Reduction and Cost Analysis (HRRCA, USEPA 2019c) as additional information supporting withdrawal of the regulatory determination. The HRRCA for perchlorate (which was presented in the 2019 proposal) provides a unique set of economic data indicators that are not available for regulatory determinations because the HRRCA is required for a proposed NPDWR under SDWA Section 1412(b)(3)(C).

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[2] The values shown in Table 1 are based on the revised UCMR 1 data. The EPA also applied statistical sampling weights to the small systems results to extrapolate to national results. There was one small system included in the statistical sample stratum which had a perchlorate measurement exceeding 18 µg/L. Accordingly, the EPA estimates that approximately 41,000 small system customers may be exposed to perchlorate greater than 18 µg/L.

but is not ~~prepared~~required to support a regulatory determination. ~~Perchlorate is a unique contaminant for which~~Accordingly, because the ~~Agency has done significant new analysis not undertaken for~~EPA initially determined that perchlorate met the criteria for regulation and began the regulatory ~~determinations. Accordingly,~~analysis process, the HRRCA was available with respect to perchlorate, and the Agency considered this comprehensive economic analysis in informing its decision to withdraw the regulatory determination.

Specifically, the HRRCA provides a description of the potential ~~quantifiable and non-quantifiable~~ benefits and costs of a drinking water regulation for perchlorate. For all potential regulatory levels considered for perchlorate (18, 56, and 90 μg/L) the total costs associated with establishing a regulation were substantially higher than the potential range of ~~quantifiable~~ benefits. The infrequent occurrence of perchlorate at levels of health concern imposes high monitoring and administrative cost burdens on public water systems and the states, while having little impact on health risk reductions and the associated low estimates of benefits.

Based on a comparison of costs and benefits estimated at the three potential regulatory levels, the EPA determined in the 2019 proposal that the benefits of establishing a drinking water regulation for perchlorate do not justify the potential costs.

A drinking water regulation for perchlorate would impose significant burden on states and water systems, mainly associated with requirements for monitoring but which would result in very few systems having to take action to reduce perchlorate levels. It is of paramount importance that water systems (particularly medium, small and economically distressed systems)

focus their limited resources on actions that ensure compliance with existing ~~NPDWR~~NPDWRs and ~~sustain~~maintain their technical, managerial, and financial capacity ~~maintain~~ to improve system operations and the quality of water being provided to their customers rather than spending resources monitoring for contaminants that are unlikely to occur.

D. What is the EPA's final regulatory determination on perchlorate?

Based on the EPA's ~~new~~ analysis of the best available public health information, and after careful review and consideration of public comments on the June 2019 proposal, the Agency is withdrawing its 2011 determination and is ~~now~~ making a final determination to not ~~to~~ regulate perchlorate. Accordingly, the EPA will not issue a NPDWR for perchlorate at this time. While the EPA has found that perchlorate may have an adverse effect on human health, based on the analysis presented in this notice and supporting record, the EPA has determined that perchlorate does not occur in public water systems ~~at~~with a frequency and at levels of public health concern and that regulation of perchlorate does not present a meaningful opportunity to reduce health risks for persons served by public water systems. This conclusion is based on the best available peer reviewed science and data collected in accordance with accepted methods on perchlorate health effects and occurrence.

IV. Summary of Key Public Comments on Perchlorate

The EPA received approximately 1,500 comments from individuals or organizations on the June 2019 proposal. This section briefly discusses the key technical issues raised by commenters and the EPA's response. Comments are also addressed in the ''Comment Response

Document for the Final Regulatory Action for Perchlorate'' (USEPA, 2020a) available at http://www.regulations.gov (Docket ID No. EPA–HQ–OW–2018–0780).

A. SDWA Statutory Requirements and the EPA's Authority

The EPA received comments stating the Agency should promulgate an MCLG and MCL for perchlorate and comments stating the Agency should not promulgate a regulation. After considering these comments the ~~Agency~~EPA has re-evaluated perchlorate in accordance with the SDWA, section 1412(b)(1)(A), which requires that the ~~EPA~~Agency promulgate a NPDWR if (i) the contaminant may have an adverse effect on the health of persons; (ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and (iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

The ~~Agency~~EPA has determined, based upon the best available peer reviewed science and data collected in accordance with accepted methods, that perchlorate does not occur ~~with~~at a frequency and at levels of public health concern, and ~~there is not~~that regulation of perchlorate does not present a meaningful opportunity for health risk reduction. ~~Therefore,~~Because perchlorate does not meet the ~~Agency has determined not~~ statutory criteria for regulation, the EPA lacks the authority to ~~promulgate~~issue a MCLG or NPDWR for perchlorate~~.~~, and is therefore withdrawing its 2011 regulatory determination and issuing this final determination to not regulate perchlorate. For more information regarding EPA's statutory authority to withdraw its regulatory determination, see Section II.C above.

B. Health Effects Assessment

Health Effects/MCLG Derivation

The ~~Agency~~EPA received comments indicating that the ~~EPA~~Agency should utilize different approaches to derive the MCLG for perchlorate including approaches that some states used to develop their perchlorate advisory levels or drinking water standards. The ~~Agency~~EPA considered a number of alternative approaches to develop the MCLG for perchlorate and in accordance with the SDWA, section 1412(e)), the Agency sought recommendations from the Science Advisory Board. The EPA derived the proposed MCLG for perchlorate based on the approach recommended by the Science Advisory Board (SAB) (SAB for the U.S. EPA, 2013). The SAB recommended that *"the EPA derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling based upon its mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters."* The EPA has implemented these recommendations and has obtained two independent peer reviews of the analysis. These peer reviewers stated that: "*Overall, the panel agreed that the EPA and its collaborators have prepared a highly innovative state-of-the-science set of quantitative tools to evaluate neurodevelopmental effects that could arise from drinking water exposure to perchlorate. While there is always room for improvement of the models,* *with limited additional work to address the committee's comments below, the current models are fit-for-purpose to determine an MCLG*" (External Peer Reviewers ~~forUSEPA~~for USEPA, 2018, p. 2).

The EPA received comments indicating the most sensitive life stages were not selected and/or considered in the Agency's approach. The EPA disagrees. Gestational exposure to perchlorate during neurodevelopment is the most sensitive time period. The NRC concluded that the population most sensitive ~~population~~ to perchlorate exposure are "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a1mn5hjprkt","properties":{"formattedCitation":"(National Research Council (NRC), 2005b)","plainCitation":"(National Research Council (NRC), 2005b)","noteIndex":0},"citationItems":[{"id":350,"uris":["http://zotero.org/groups/945096/items/TN6HMC9D"],"uri":["http://zotero.org/groups/945096/items/TN6HMC9D"],"itemData":{"id":350,"type":"book","title":"Health Implications of Perchlorate Ingestion","publisher":"National Academies Press","publisher-place":"Washington, DC","event-place":"Washington, DC","author":[{"literal":"National Research Council (NRC)"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. In addition, there is clear evidence that disrupted maternal thyroid hormone levels during gestation can impact neurodevelopment later in life (Alexander et al., 2017; Costeira et al., 2011; Endendijk et al., 2017; Ghassabian, Bongers-Schokking, Henrichs, Jaddoe, & Visser, 2011; Glinoer & Delange, 2000; Glinoer & Rovet, 2009; Gyllenberg et al., 2016; Henrichs et al., 2010; Korevaar et al., 2016; Morreale de Escobar, Obregón, & Escobar del Rey, 2004; Noten et al., 2015; Pop et al., 2003, 1999; SAB for the U.S. EPA, 2013; Thompson et al., 2018; van Mil et al., 2012; Wang et al., 2016; Zoeller & Rovet, 2004; Zoeller et al., 2007). ~~The EPA's analysis concludes that~~ The available data demonstrate that the fetus of the first trimester pregnant mother, when compared to other life-stages, experiences the greatest impact from ~~equivalent doses~~the same dose of perchlorate ~~exposure~~, which is described in detail in Section 6 of the document "Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (USEPA, 2019a). ~~In addition, the EPA disagrees~~Some commenters suggested that the bottle-fed ~~infants are the most~~infant is a more sensitive ~~population~~ life-stage. The EPA disagrees as described in the January 2017 Peer Review Report on the original Biologically Based Dose Response (BBDR) model, the bottle-fed infant's thyroid hormone levels were not impacted by doses of perchlorate up to 20 µg/day (External Peer Reviewers for USEPA, 2017). This lack of any impact is due primarily to the iodine in the formula, which offsets the impact of perchlorate on the thyroid.

The ~~Agency~~EPA received comments advocating for the use of ~~a~~the population-based approach~~:~~ evaluating the shift in the proportion of a population that would fall below a hypothyroxinemic cut point under a perchlorate exposure scenario. The ~~Agency~~EPA chose to develop the MCLG using dose-response functions from the epidemiological literature to

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estimate neurodevelopmental impacts in the offspring of pregnant women exposed to perchlorate. The EPA selected this proposed approach because it is consistent with the SDWA's definition of a MCLG to avoid adverse health effects and because it is most consistent with the SAB recommendations. In addition, the fact that thyroid hormone levels vary by reference population and that there is not a defined value representing hypothyroxinemia makes the population-based approach less desirable than the approach selected (USEPA, ~~2018b~~2018).

End Point Selection/Basis

The ~~Agency~~EPA received comments regarding the magnitude of an IQ change which should be used in ~~considering~~deriving the MCLG. ~~Many comments stated that the Agency should at most consider a 1% IQ change. However, several commenters stated a 3% change is too small to have a meaningful impact and suggested the Agency consider a higher IQ percent change.~~ The ~~Agency's~~EPA's proposed MCLG was based upon avoiding a 2% change in IQ in the most sensitive life stage and the EPA also requested comment on alternative options for the MCLG that would respectively avoid 1% or 3% change in IQ in the most sensitive ~~lifestage~~life stage. Many comments stated that the EPA should at most consider a 1% IQ change. However, several commenters stated a 3% change is too small to have a meaningful impact and suggested the EPA consider a higher IQ percent change.

The EPA uses a variety of science policy approaches to select points of departure for developing regulatory values. For instance, in noncancer risk assessment the EPA often uses a percentage change in value. When assessing toxicological data, a 10 ~~percent~~% extra risk (for discrete data), or a 1 standard deviation (i.e., 15 IQ points) change from the mean (for continuous data) is often used (USEPA, 2012). A smaller response to inform a POD has been applied when using epidemiological literature because there is an inherently more direct relationship between the study results and the exposure context and health endpoint.

Given the difficulty in identifying a response below which no adverse impact occurs when considering a continuous outcome in the human population, the EPA looked to its Benchmark Dose Guidance (2012) for insight regarding a starting point. Specifically, ‘‘[a] BMR of 1% has typically been used for quantal human data from epidemiology studies’’ (p. 21, USEPA, 2012). For the specific context of setting an MCLG for perchlorate, the EPA ~~made a policy decision to evaluate~~evaluated the level of perchlorate in water associated with a 1 ~~percent~~% decrease, a 2 ~~percent~~% decrease, and a 3 percent decrease in the mean population IQ (i.e., 1, 2 and 3 IQ points).

In evaluating the frequency and level of occurrence of perchlorate in drinking water the ~~Agency~~EPA has found that perchlorate does not occur with frequency even at the lowest alternative MCLG of 18 μg/L which is based upon avoiding a 1% change in IQ in the most sensitive ~~lifestage~~life stage.

The ~~Agency~~EPA received comments that the proposed MCLG did not incorporate an adequate margin of safety to comply with the SDWA. The ~~Agency~~EPA disagrees that ~~there was a failure~~it failed to use an adequate margin of safety. The ~~Agency's~~EPA's assessment focused upon the most sensitive subset of the population, specifically offspring whose mothers had low (75 µg/day) iodine intake and were ~~hypothyroximemic~~hypothyroxinemic (fT4 in the lowest 10th percentile of the population). In addition, to account for uncertainties and to ensure the most sensitive subset of the population is protected ~~within~~with an adequate margin of safety, a 3-fold uncertainty factor was applied to the proposed MCLG calculation (USEPA, 2019a). More discussion on the uncertainty factor is presented in the section "Consideration of Uncertainties."

The EPA received some comments stating that the selection of the study for informing the relationship between maternal hormone levels (fT4) and IQ was inadequately described. Other comments ~~support~~supported the ~~Agency's~~EPA's study selection. The EPA concludes that selection of the Korevaar et al. (2016) study is appropriate because that study provides the most robust data available with a clear measure of neurodevelopment that can be expressed as a function of changing maternal fT4 exposure, which is necessary to the development of the model.

BBDR and PBPK Models

The ~~Agency~~EPA received comments indicating the BBDR model was not transparent, scientifically valid, or based on robust data. The ~~Agency~~EPA disagrees. The model represents the best available peer reviewed science and ~~utilizes~~uses the best available data to inform a MCLG for perchlorate. The EPA does not believe there is a significant lack of transparency with respect to the assumptions related to the BBDR model. Appendix A of the EPA's Proposed MCLG Approaches report outlines the justification for all assumptions used in the development of the BBDR model (USEPA, 2019a). The EPA also disagrees with the assertion the BBDR model is far too uncertain to be relied upon as the basis for the derivation of the RfD. The EPA has used the best available science to calibrate the pharmacokinetic aspects of the BBDR model. The development of the BBDR model was ~~performed~~ in response to SAB recommendations and a model was deemed to be a more ~~superior~~refined approach to estimating a dose-response relationship between perchlorate exposure and maternal fT4 than anything that was available in the current scientific literature. The EPA disputes the claim that there are issues with the scientific validity of the BBDR model as the Agency conducted a peer review of the approach proposed and the reviewers stated the approach was "fit for purpose" to inform a MCLG for perchlorate (External Peer Reviewers for U.S. EPA, 2018, p. 2).

Consideration of Uncertainties

The ~~Agency~~EPA received comments on the ~~EPA's~~Agency's use of Uncertainty Factors (UFs~~).~~); with most commenters ~~suggested~~suggesting that the EPA should consider a higher UF. The ~~Agency~~EPA thoroughly considered the application of UFs when deriving the RfDs and followed guidance presented in "A review of the reference dose and reference concentration processes" (USEPA, 2002). The ~~Agency believes~~EPA concluded that the UFs are adequately justified and subsequently no changes have been made. Justification for each of the UFs ~~described in this comment~~ can be found in Section 11 of the Agency's MCLG Derivation report (USEPA, 2019a).

The ~~Agency~~EPA selected a UF of 3 for inter-individual variability because the Agency specifically modeled groups within the population that are identified as likely to be at greater risk ~~to~~of the adverse effects from perchlorate in drinking water (i.e., the fetus of the iodide deficient pregnant mother). The ~~Agency~~EPA selected model parameters to account for the most sensitive individuals in that group (i.e., muted TSH feedback, low fT4 values, low-iodine intake). As discussed in the MCLG Derivation report, the EPA has attempted to select the most appropriate inputs to protect the most sensitive population with an adequate margin of safety (USEPA, 2019a). The ~~Agency~~EPA has determined that the selection of a UF of 3 for inter-individual variability is justified. As described in the MCLG Derivation report, because the output from the BBDR model is specific to the sensitive population ~~and therefore the Agency has made no change in~~the EPA concluded that the UF of 3 is appropriate. In regards to variation in sensitivity among the members of the human population (i.e., inter-individual variability), section 4.4.5.3 of the EPA guidance "A review of the reference dose and reference concentration process" (USEPA, 2002) document states, "In general, the Technical Panel reaffirms the importance of this UF, recommending that reduction of the intraspecies UF from a default of 10 be considered only if data are sufficiently representative of the exposure/dose-response data for the most susceptible subpopulation(s). Similar to the interspecies UF, the intraspecies UF can be considered to consist of both a toxicokinetic and toxicodynamic portion (i.e. 10^0.5 each)" (USEPA, 2002). Given that the BBDR model significantly accounts for differences within the human population, the full UF of 10 is not warranted.

One commenter suggested using a UF greater than 1 to account for ~~LOAEL-to-NOAEL~~the extrapolation, of the lowest-observed adverse effect level (LOAEL) to the no-observed-adverse-effect-level (NOAEL). LOAELs and NOAELs were not identified or used by the EPA in its assessment because the Agency ~~has determined that the IQ~~ employed a sophisticated BBDR modeling approach, which was coupled with extrapolation to changes ~~presented as options in the 2019 proposal~~in IQ using linear regression, to determine a POD that would not be expected to represent ~~NOAELs,~~an adverse effect. Therefore, ~~including~~ a UF ~~to account for extrapolating from a LOAEL to a NOAEL~~of 1 is ~~not needed. Additional~~appropriate. Other commenters suggested incorporating UFs for database deficiencies. Based on the findings of the NRC report, the EPA has previously concluded that this UF was not needed for deficiencies in the perchlorate database (NRC, 2005; USEPA, 2005a). The EPA believes that a UF of 1 to account for database deficiencies is still appropriate given that the state of the perchlorate database has only increased since 2005.

C. *Occurrence Analysis*

The EPA received comments suggesting that the revised UCMR 1 data did not provide an adequate estimate ~~about~~of the perchlorate occurrence in drinking water systems. Some commenters indicated that the age of the collected data rendered the occurrence analysis obsolete and overestimated, since it no longer captures current lower contamination conditions ~~which~~that have been achieved due to mitigation measures taken in the Colorado River Basin. Other commenters criticized the EPA for replacing UCMR 1 data with compliance data for the States of California and Massachusetts.

The EPA recognizes that changes in perchlorate levels (increasing or decreasing) may have occurred in water systems since the UCMR 1 samples were collected between 2001 to 2005. The ~~Agency~~EPA updated the UCMR 1 data set to improve its accuracy in representing the current conditions for states that have enacted perchlorate regulations since the UCMR 1 monitoring was conducted. As outlined in the June 26, 2019 proposal, the EPA updated occurrence data for California and Massachusetts with current compliance data as reported by the states. Systems from these two states that were sampled during the UCMR 1 and that had reported perchlorate detections were updated with more recently measured values taken from current compliance monitoring data from Consumer Confidence Reports and state-level perchlorate compliance monitoring data to match corresponding water systems and entry points ~~between the two sources~~.

The EPA has determined that the updated UCMR 1 data are the best available data collected in accordance with accepted methods on the frequency and level of perchlorate occurrence in drinking water on a national scale.

V. Conclusion

With this withdrawal of the 2011 perchlorate regulatory determination and final determination to not ~~to~~ regulate perchlorate, the EPA announces that there will be no NPDWR for perchlorate at this time. The EPA could consider re-listing perchlorate on the CCL and could proceed to regulation in the future if the occurrence or health risk information changes. As with other unregulated contaminants, the EPA ~~could address the~~will consider addressing limited instances of elevated levels of perchlorate by working with the affected system and state, as appropriate.

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List of Subjects in 40 CFR Parts 141 and 142

Administrative practice and procedure, Chemicals, Indians-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated:____________________

____

Andrew ~~R.~~ Wheeler,

Administrator.

MEMORANDUM

SUBJECT: Notice of Final Action on Perchlorate
(Tier 1 Action; SAN 5555; RIN 2040-AF28) – **ACTION MEMORANDUM**

FROM: David P. Ross
Assistant Administrator (4101M)

THRU: Office of Policy (1803A)
Office of Executive Secretariat (1105A)

TO: Andrew J. Wheeler
Administrator (1101A)

PURPOSE
Attached for your signature is the action titled "Notice of Final Action on Perchlorate."

On February 11, 2011, the EPA published a determination to regulate perchlorate in drinking water (76 FR 7762). On June 26, 2019 (84 FR 30524), the EPA published the proposed National Primary Drinking Water Regulation (NPDWR) for Perchlorate and requested public comments on multiple alternative actions, including withdrawing the Agency's 2011 determination to regulate perchlorate. The EPA received approximately 1,500 comments on the proposed rule.

In this notice, the EPA is withdrawing the 2011 Regulatory Determination and is making a final determination not to regulate perchlorate based on the Agency's consideration of public comments and the best available information.

DEADLINE/TIMELINE
Section 1412(b)(1)(A) of the Safe Drinking Water Act (SDWA) requires the EPA to issue a proposed NPDWR within 24 months of the final regulatory determination and a final NPDWR within 18 months after the proposal. However, when the EPA consulted with the Science Advisory Board (SAB) regarding a planned methodology for deriving the maximum contaminant level goal (MCLG) for perchlorate, the Agency received recommendations to develop a physiologically based pharmacokinetic model (i.e., a biologically based dose-response model (BBDR)) to predict the effects of perchlorate exposure on thyroid function in pregnant women and their children, instead. The EPA collaborated with Food and Drug Administration scientists to perform the modeling recommended by the SAB and completed the analysis and associated peer reviews in March 2018. This delayed the EPA in proposing a NPDWR within 24 months.

In February 2016, the Natural Resources Defense Council (NRDC) filed a lawsuit for failure of the EPA to perform its mandatory duties of proposing and finalizing a regulation for perchlorate in accordance with timelines provided in the SDWA. On October 18, 2016, the U.S. District Court for the Southern District of New York entered a Consent Decree, requiring the EPA to sign for publication a proposal for a MCLG and NPDWR for perchlorate in drinking water no later than October 31, 2018, and to sign for publication a final MCLG and NPDWR for perchlorate in drinking water no later than December 19, 2019. The Court later extended the deadline for the EPA to propose a MCLG and NPDWR for perchlorate in drinking water to May 28, 2019, and extended the date for signature of a final MCLG and NPDWR no later than June 19, 2020.

In compliance with the deadline established in the Consent Decree, on May 23, 2019, the Administrator signed a proposed rulemaking notice seeking public comment on a range of options regarding the regulation of perchlorate in public drinking water systems. The EPA published the proposed rule in the *Federal Register* on June 26, 2019. The public comment period for the proposal ended on August 26, 2019, and the EPA received approximately 1,500 comments.

DESCRIPTION of the ATION

Perchlorate is an inorganic anion that occurs naturally. It is also manufactured as an oxidizer for rockets, missiles, and fireworks and can be an impurity in hypochlorite disinfectants. The public may be exposed to perchlorate through food and drinking water. At certain levels, perchlorate can prevent the thyroid gland from getting enough iodine, which can affect thyroid hormone production. For pregnant women with low iodine levels, sufficient changes in thyroid hormone levels may cause changes in the child's brain development. For infants, changes to thyroid hormone function can also impact brain development.

The SDWA sets forth three criteria that must be met for the EPA to issue a MCLG and promulgate a NPDWR. Specifically, the EPA must determine that (1) "the contaminant may have an adverse effect on the health of persons;" (2) "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern;" and (3) "in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems" (SDWA 1412(b)(1)(A)).

In the attached notice, the EPA concludes that, based on new data and the Agency's analysis since the issuance of the 2011 Regulatory Determination, perchlorate does not in fact meet the statutorily prescribed criteria for regulation. The new data and analysis indicate that perchlorate does not occur in public water systems with a frequency and at levels of public health concern. Specifically, the new peer-reviewed health effects analysis resulted in the health based proposed MCLG and proposed alternative MCLGs for perchlorate that are higher concentrations in drinking water (18 – 90 µg/L) than the concentrations that the EPA considered to be levels of public health concern in the Agency's analysis for the determination to regulate in 2011 (1-47 µg/L). In addition, the updated occurrence analysis shows that the frequency of occurrence of perchlorate in public water systems at levels exceeding any of the alternative proposed MCLGs (0.38% - 0.02%) is significantly lower than the frequency considered in the EPA's analysis for the 2011 Regulatory Determination (4% - 0.39%). Based on this information, the

EPA is announcing the Agency's conclusion that perchlorate does not occur in public water systems "with a frequency…of public health concern" and, therefore, regulation of perchlorate does not present a "meaningful opportunity for health risk reduction for persons served by public water systems" as required for regulation under the SDWA. Accordingly, perchlorate no longer meets the statutory criteria for regulation because the EPA does not have the authority to issue a MCLG or promulgate a NPDWR for perchlorate.

Therefore, the EPA is not issuing a final MCLG or NPDWR for perchlorate. However, the EPA maintains the authority to re-list perchlorate on future Contaminant Candidate Lists and proceed with regulating perchlorate in the future if occurrence or risk information changes. The EPA will consider addressing limited instances of elevated levels of perchlorate by working with the affected system and state, as appropriate.

STAKEHOLDER INVOLVEMENT and ANTICIPATED RESPONSE

The EPA considered the approximately 1,500 comments that were submitted on the proposed regulation. The EPA also consulted with the National Drinking Water Advisory regarding the proposed regulation. The EPA expects a variety of reactions and responses from stakeholders. The NRDC will likely sue the EPA for failure to comply with the Consent Decree and will likely challenge the Agency's authority to withdraw a Regulatory Determination. Officials from the States of California and Massachusetts, public health groups and environmental groups will likely state that a low perchlorate maximum contaminant level is needed to protect children's health. Industry groups, including the American Water Works Association, the Perchlorate Study Group, the American Chemistry Council, and the U.S. Chamber of Commerce will support the decision not to regulate perchlorate in drinking water. These groups will agree with the EPA's determinations that perchlorate does not occur frequently at levels of public health concern and there is not a meaningful opportunity for health risk reduction for persons served by public water systems.

INTERNAL DEVELOPMENT and REVIEW PROCESS

The attached notice reflects the direction provided by the Administrator in the Options Selection meetings held on January 9 and March 18, 2020. The Office of Water (OW) convened a Final Agency Review meeting for this action on May 7, 2020. The following offices concurred without comment: the Office of Research and Development, the Office of Land and Emergency Management, the Office of Air and Radiation, and the Office of Chemical Safety and Pollution Prevention. The following offices concurred with comment: the Office of General Counsel (OGC), the Office of Policy (OP), and the Office of Children's Health Protection (OCHP). The OW has incorporated revisions identified in the comments from the OGC. The OW has also incorporated most of the suggested revisions identified by the OP, the key exception being that we are not incorporating OP's recommendation to not list the cost benefit analysis as a factor in the decision to withdraw the regulatory determination. The OW has worked with OGC to incorporate language that clarifies that this does not set a precedent for future regulatory determinations. The OW is not incorporating the majority of recommendations made by the OCHP, which address the health effects and occurrence analysis and are issues we have evaluated previously, including in response to OCHP's input on the proposal and in response to public comments.

INTERAGENCY REVIEW
The Office of Management and Budget initiated review of the *Federal Register* notice: "Notice of Final Action on Perchlorate" on [date placeholder].

PEER REVIEW
For the proposed rulemaking, the OW followed the EPA's Peer Review Handbook and Agency policy titled "Conflicts of Interest Review Process for Contractor-Managed Peer Reviews of EPA HISA and ISI Documents" when conducting the peer review of models used to derive the proposed MCLGs for perchlorate. The EPA convened an independent peer review panel to evaluate the BBDR models in 2017 and a second, expert peer review panel in 2018 to evaluate the update of the BBDR model and approaches to link the BBDR model output to neurodevelopment endpoints in epidemiology studies to derive an MCLG. The EPA also sought input from the SAB, as required by the SDWA, prior to developing the proposed MCLGs.

RECOMMENDATION
I recommend that you sign the attached *Federal Register* notice titled "Notice of Final Action on Perchlorate."

Attachments (2)

Message

From: Mclain, Jennifer [Mclain.Jennifer@epa.gov]
Sent: 1/7/2020 10:51:23 PM
To: Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]
CC: Aguirre, Janita [Aguirre.Janita@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Nagle, Deborah [Nagle.Deborah@epa.gov]; Behl, Betsy [Behl.Betsy@epa.gov]; Wendelowski, Karyn [wendelowski.karyn@epa.gov]
Subject: revised perchlorate briefing
Attachments: Option Selection for Perchlorate 1-9-2020 Administrator briefing 1-7-2020 clean draft.docx; Option Selection for Perchlorate 1-9-20v2.docx

Charlotte
Attached is a revised perchlorate briefing document per our meeting with Dave this morning. I've also attached the track changes version so you can see the specifics of where we made changes.
Please let us know if you have any questions.
Jennifer

Jennifer L. McLain, Director
Office of Ground Water and Drinking Water
U.S. EPA

Reductions of Perchlorate in Drinking Water

May 2020

LEVELS OF PERCHLORATE IN DRINKING WATER HAVE DECLINED

Perchlorate is commonly used in solid rocket propellants, munitions, fireworks, airbag initiators for vehicles, matches, and signal flares. Perchlorate may occur naturally, particularly in arid regions such as the southwestern U.S. and can be found as a byproduct in hypochlorite solutions used for treating drinking water and nitrate salts used to produce fertilizers, explosives, and other products.

At certain levels, perchlorate can prevent the thyroid gland from getting enough iodine, which can affect thyroid hormone production. For pregnant women with low iodine levels, sufficient changes in thyroid hormone levels may cause changes in the child's brain development. For infants, changes to thyroid hormone function can also impact brain development.

The EPA finds that perchlorate levels in drinking water supplies have declined since the EPA published a final determination to regulate perchlorate in 2011. The 2011 determination was based on occurrence data collected between 2001 and 2005 under the 1st Unregulated Contaminant Monitoring Rule (UCMR1). At that time, the Agency found that over 4% of water systems tested detected perchlorate and that between 5.2-16 million people may be exposed to perchlorate in drinking water.

In the June 2019 National Primary Drinking Water Regulation for Perchlorate proposal, EPA presented an updated occurrence analysis that demonstrates that the levels of perchlorate in drinking water and sources of drinking water have decreased since the UCMR1 data collection. This document summarizes the main factors contributing to the decrease in perchlorate levels which include: 1) the promulgation of a drinking water regulation for perchlorate in California and Massachusetts; and 2) the ongoing remediation efforts in the state of Nevada to address perchlorate contamination in groundwater adjacent to the lower Colorado River upstream of Lake Mead. This document also summarizes the status of the 15 water systems that reported elevated levels of perchlorate under the UCMR 1. Finally, this document summarizes actions to reduce levels of perchlorate through remediation activities at perchlorate contaminated sites and through proper storage and handling of hypochlorite solutions.

California & Massachusetts Drinking Water Regulations

Perchlorate occurrence in drinking water systems in the state of California accounted for approximately 60% of all perchlorate detections reported under UCMR1. In 2007, California promulgated a drinking water regulation for perchlorate of 6 ppb. At the time UCMR1 data collection was completed in 2005, there were 30 systems with perchlorate occurrence above 6 ppb in California. The EPA compared entry point data collected under UCMR1 to current entry point monitoring data for water systems in California. As of 2019, only one system in California is in violation of the state standard of 6 ppb, and no systems had perchlorate concentrations above 18 ppb (the lowest level proposed by EPA in June 2019).

In addition, Massachusetts adopted a drinking water standard for perchlorate of 2 ppb in 2006. One water system in Massachusetts had a perchlorate detection in UCMR1. Based on a review of current publicly available information, there are no systems in Massachusetts in violation of the state standard.

Reduction of Perchlorate Levels in the Southwest

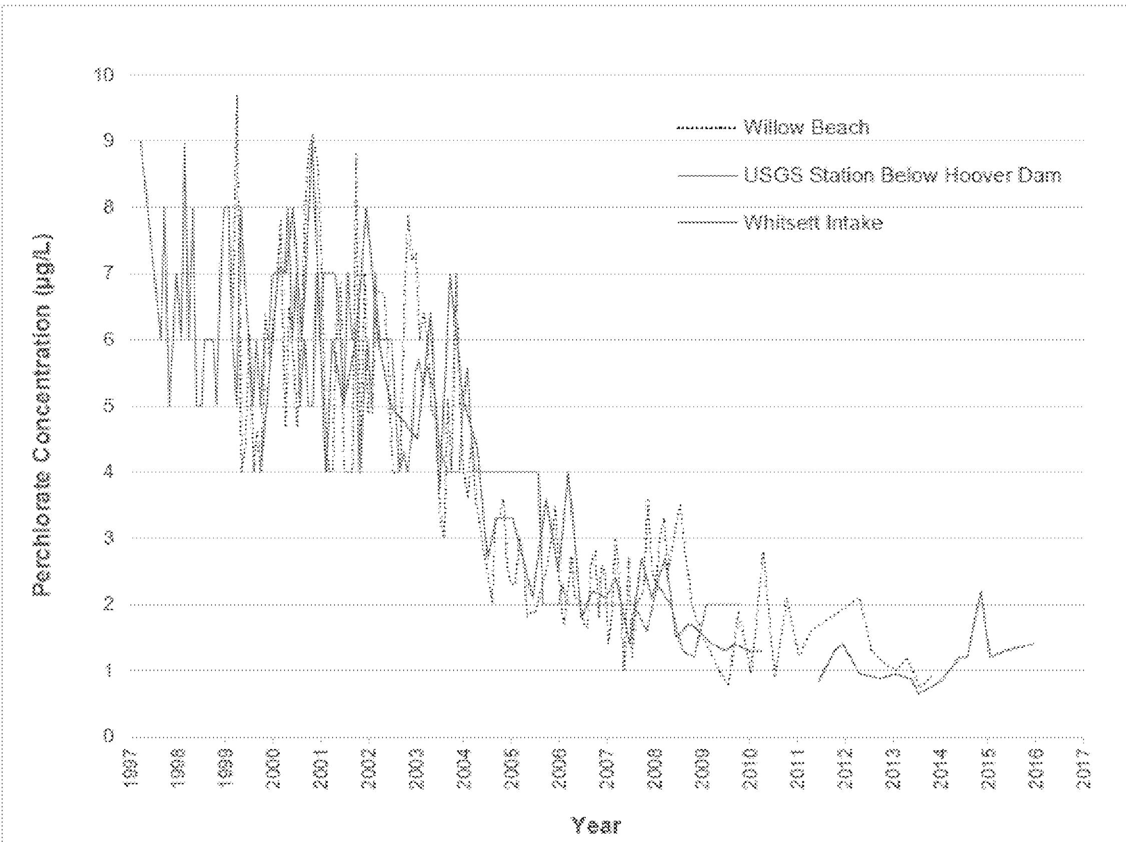
Lower Colorado River Case Study

The Lower Colorado serves as the primary source of water for the Metropolitan Water District (MWD) of Southern California and as a source for several public water systems in Arizona and Nevada. The primary source of perchlorate along the Lower Colorado is manufacturing facilities near Henderson, Nevada. Contaminated groundwater had seeped into the Las Vegas Wash, which drains into Lake Mead and then the Colorado River. Full remediation was active at two industrial sites in the Las Vegas Valley between 2002 and 2006.

The data provided by the Nevada Division of Environmental Protection (NDEP) and the Southern Nevada Water Authority show a decreasing trend in perchlorate concentrations over the last decade, especially after point-source remediation efforts began in 2002. Perchlorate samples were collected at a USGS site just below the Hoover Dam; Willow Beach, Arizona; and Whitsett, California. Whitsett is an MWD source water intake point. Perchlorate raw water sample results from 1997 to 2016 from the USGS station, Willow Beach, and Whitsett sites are shown in Exhibit A.

For the USGS site, perchlorate concentrations ranged between 4 to 9 ppb prior to 2002. After 2009, most concentrations were between 1 and 2 ppb. Willow Beach perchlorate concentrations were 4 to 10 ppb prior to 2002 and were 1 to 3 ppb after 2009. Whitsett perchlorate concentrations were between 4 and 9 ppb from 1997 until 2005. After 2006, the majority of perchlorate concentrations were below 2 ppb. Thus, at all monitoring locations, there was a downward trend in perchlorate levels in the Lower Colorado River. Note that perchlorate analytical methods and their respective detection limits changed over the monitoring period (i.e., perchlorate could be measured at lower levels).

Exhibit A. Perchlorate Raw Water Sample Results from the Willow Beach, USGS Station, and Whitsett Sampling Sites, 1997 – 2016



Arizona Department of Environmental Quality (ADEQ) Case Study

In 1999, the ADEQ conducted a perchlorate occurrence study of Arizona water resources. Samples were collected from the Colorado River, Central Arizona Project (CAP) Canal, and various groundwater sources in the Phoenix area. Perchlorate concentrations of 480 ppb were found in Lake Mead and along the Colorado River main stem and the CAP Canal the results were between 11 ppb and non-detection (at that time defined by Arizona as less than 4 ppb).

In 2000 and 2001, the City of Phoenix conducted a second round of perchlorate monitoring at the same sample locations used in the 1999 ADEQ study, and monitoring results showed decreased perchlorate levels along the Colorado River main stem and in the CAP Canal.

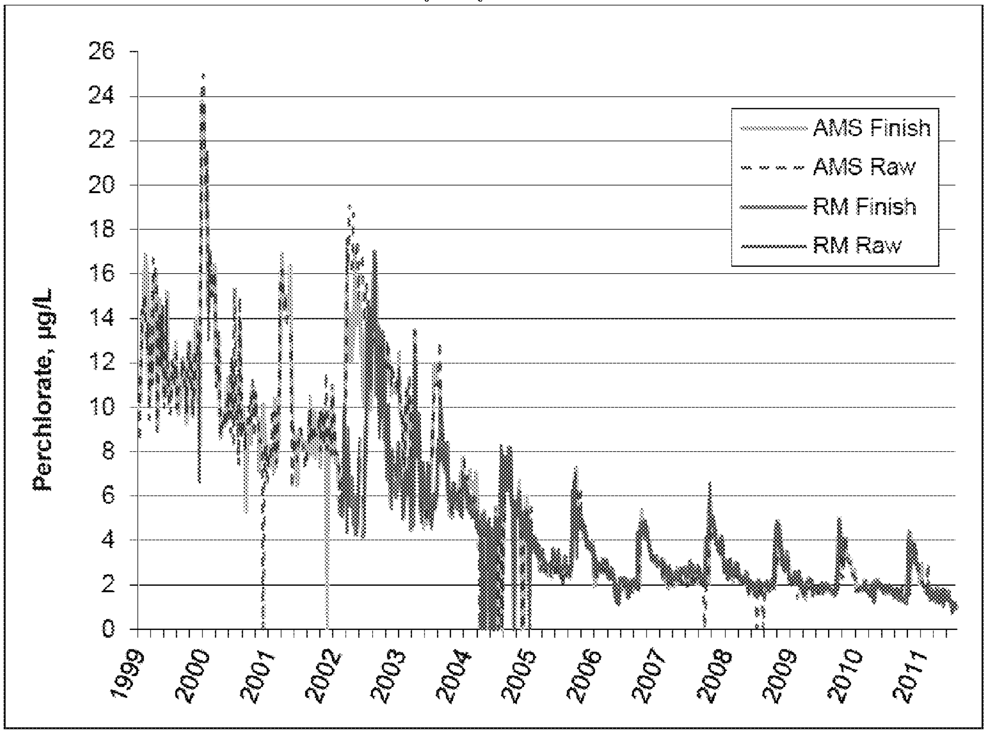
In 2004, the City of Phoenix collected 392 finished water samples and found 39 perchlorate detections ranging from 2 ppb (the Arizona specified reporting limit) and 5.4 ppb. Raw water samples were also collected at 67 sites that included Colorado River water, man-made recreational impoundments, canals, wells, agricultural areas and ground water recharge projects. Perchlorate was detected in 24 samples from 24 different sites and perchlorate concentrations ranged from non-detection to 7.4 ppb.

Nevada Division of Environmental Protection (NDEP) Case Study

The NDEP evaluated data from two water treatment plants: Alfred Merritt Smith Water Treatment Facility and River Mountains Water Treatment Facility. The plants are part of the Southern Nevada Water System, which sources water from the Lower Colorado River.

Perchlorate levels found in both raw and finished water decreased in a relatively consistent and an overall significant amount over the 13-year sampling period, as shown in Exhibit B (1999 – 2011).

Exhibit B. Perchlorate Raw and Finished Water Data from Alfred Merritt Smith (AMS) and River Mountains (RM) Treatment Plants



Although the laboratory analytical methods changed over the period of sampling i.e., perchlorate could be measured at lower levels, the time period and range of decreases mirror those identified in the Lower Colorado River case study.

STATUS OF WATER SYSTEMS WITH UCMR1 RESULTS > 18 PPB

In its 2011 final regulatory determination for perchlorate, the EPA relied upon the UCMR1 data as the best available data on the frequency and level of perchlorate in drinking water. In the June 2019 National Primary Drinking Water Regulation for Perchlorate proposal, EPA presented updated occurrence analysis that demonstrates that the levels of perchlorate in drinking water and sources of drinking water have decreased since the UCMR1 data collection.

Using the updated UCMR1 data presented in the June 2019 proposal, the EPA identified 15 water systems located across 12 states with at least one reported result that was greater than 18ppb[1]. Although systems are not required to take actions to reduce perchlorate in drinking water, the EPA found that perchlorate levels have been reduced in many of the systems. The status of each of these systems is described in Table 1 below.

To obtain updated data and/or information regarding perchlorate levels, the EPA reviewed Consumer Confidence Reports and other publicly available data, as well as published studies. In addition, the EPA contacted some water systems for information about current perchlorate levels.

Table 1: Update on Systems with Perchlorate levels above 18 ppb in the UCMR 1 (2001-2005)

State	System Name	Range of UCMR 1 Results (ppb)[2]	Update on Mitigation and Levels of Perchlorate
Florida	Sebring Water	ND-70	EPA contacted the Sebring system in January 2020. Operations personnel indicated that no follow-up/updated monitoring data for perchlorate is available.
Florida	Manatee County Utilities Dept	ND-30	Researchers contacted the system to identify the source of perchlorate. System personnel attributed the sole perchlorate detection under UCMR1 to analytical error. System personnel indicated that three other quarterly samples collected under UCMR1 as well as other subsequent perchlorate sampling efforts were non-detect. Source: AWWA (2008)
Georgia	Oconee Co.-Watkinsville	38 (single sample)	Researchers contacted the system and found that a perchlorate contaminated well was removed from service in 2003. The system indicates that perchlorate is no longer detected. Source: Luis et al. (2019)
Louisiana	St. Charles Water District 1 East Bank	ND-24	EPA was not able to identify updated data on perchlorate levels for this system.

[1] Eighteen (18) ppb is the lowest alternative maximum contaminant level goal the Agency considered in the June 2019 proposal.
[2] Values have been rounded. ND describes a sampling event where perchlorate was not detected at or above the UCMR 1 minimum reporting level of 4 ppb.

State	System Name	Range of UCMR 1 Results (ppb)[2]	Update on Mitigation and Levels of Perchlorate
Maryland	City of Aberdeen	ND-19	The system's 2018 Consumer Confidence Report (CCR) indicates that perchlorate was not detected. According to the Maryland Department of Environment, perchlorate was not detected in this system in 2019. In addition, researchers contacted the system and found that there has been no detection of perchlorate since treatment was installed in 2009. Source: Luis et al. (2019)
Maryland	Chapel Hill - Aberdeen Proving Grounds	ND-20	EPA contacted the Chapel Hill System in January 2020. Water system personnel indicate that the Chapel Hill WTP was taken off-line and was replaced with a new treatment plant and five new production wells. The new treatment plant started operations on January 27, 2020. System personnel also indicate that monitoring was conducted in November 2019 and perchlorate was not detected in either the source well water or the finished water. In addition, according to the Maryland Department of Environment, perchlorate was not detected in this system in 2019.
Mississippi	Hilldale Water District	ND-20	EPA contacted the Hilldale System in January 2020. Water system personnel indicated that no follow-up/updated monitoring data for perchlorate is available.
New Mexico	Deming Municipal Water System	15-20	Data from EPA's SDWIS/FED indicates that the entry point that reported detections in UCMR1 (Well #3) is now inactive (i.e., the contaminated source is no longer in use). Source: SDWIS/FED (2016).
Nevada	City of Henderson	6-23	Researchers report that the perchlorate levels described in the system's CCR ranged from non-detect to 9.7 ppb. Source AWWA (2008).
Ohio	Fairfield City PWS	6-27	EPA contacted the Fairfield City System in January 2020. Water system personnel indicated that follow-up monitoring was

State	System Name	Range of UCMR 1 Results (ppb)[2]	Update on Mitigation and Levels of Perchlorate
			conducted after UCMR1, between 2002 and 2004. The Ohio EPA provided copies of the follow-up monitoring results which indicate that results at the entry point ranged from non-detect to 13 ppb.
Ohio	Hecla Water Association-Plant PWS	ND-32	EPA contacted the Hecla Water Association System in January 2020. Water system personnel indicated that that no follow-up/updated monitoring data for perchlorate is available.
Oklahoma	Enid	ND-30	EPA reviewed Oklahoma's monitoring data and did not find any monitoring results reported for perchlorate.
Pennsylvania	Meadville Area Water Authority	ND-33	EPA contacted the Meadville System in January 2020. Water system personnel indicated that no follow-up/updated monitoring data for perchlorate is available.
Puerto Rico	Utuado Urbano	ND-420	EPA contacted the Puerto Rico Aqueduct and Sewer Authority (PRASA) in January 2019. PRASA personnel indicated that no updated monitoring data for perchlorate is available. *NOTE: The PRASA personnel stated that the Utuado water system was significantly impacted by hurricane Maria and monitoring records from years prior to 2017 were lost.*
Texas	City of Levelland	ND-32	Researchers found that a water storage tank was the source of perchlorate contamination, the wells feeding the tank were tested by the state and perchlorate was not detected. The water tank was shut off from service. Source: Luis et al. (2019).

ACTIONS TO REDUCE PERCHLORATE IN THE ENVIRONMENT AND DRINKING WATER

Perchlorate Contamination in the Environment

The EPA addresses perchlorate contamination in the environment through its authorities under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), known also as Superfund. There are around 60 Superfund sites conducting remediation activities for perchlorate. These sites are located in the states of Alabama, Arizona, California, Massachusetts, Maryland, North Carolina, Oregon, Texas and West Virginia. The status of these sites is provided in Table 2 below.

Table 2: CERCLA Sites Addressing Perchlorate

State	Site Name	Federal Facility?	NPL list?	Media Type	Status*
AL	USARMY/NASA Redstone Arsenal+	Y	Y	Groundwater	Construction underway
AZ	Apache Powder Co.+	N	Y	Groundwater, Soil	Construction complete
AZ	Gila River Indian Community Toxaphene Site	N	N	Soil	Early action
AZ	Pacific Waste Disposal Services	N	N	Liquid Waste	Early action
AZ	Phoenix-Goodyear Airport Area	N	Y	Groundwater	Construction underway
CA	Aerojet General Corp.+	N	Y	Groundwater, Soil	Construction underway
CA	Edwards Air Force Base+	Y	Y	Soil, Groundwater, Debris	Construction underway
CA	El Toro Marine Corps Air Station	Y	Y	Groundwater	Construction underway
CA	Jet Propulsion Laboratory (NASA)+	Y	Y	Groundwater	Construction underway
CA	Lawrence Livermore Natl Lab (Site 300) (USDOE)+	Y	Y	Groundwater	Construction underway
CA	Mcclellan Air Force Base (Ground Water Contamination)	Y	Y	Groundwater	Construction underway
CA	Mojave River Pyrotechnics Site	-	-	Soil	Early action
CA	Rockets, Fireworks, And Flares Site+	N	Y	Groundwater	Construction underway
CA	San Fernando Valley (Area 1)	N	Y	Groundwater	Construction underway
CA	San Gabriel Valley (Area 1)+	N	Y	Groundwater	Construction underway
CA	San Gabriel Valley (Area 4)	N	Y	Groundwater	Construction underway

State	Site Name	Federal Facility?	NPL list?	Media Type	Status*
MA	Otis Air National Guard Base/Camp Edwards+	Y	-	Groundwater	Construction complete
MD	Indian Head Naval Surface Warfare Center	Y	-	Soil	Construction underway
MD	Ordnance Products, Inc.+	N	Y	Groundwater	Construction complete
MD	USN Naval Surface Warfare Ctr-White Oak+	Y	-	Groundwater	Construction underway
NC	Chemtronics, Inc.	N	Y	Groundwater	Construction complete
OR	Portland Harbor+	N	Y	Groundwater, Sediment, Fish Tissue, Surface Water	Design underway
TX	Longhorn Army Ammunition Plant+	Y	Y	Soil, Groundwater, Surface Water, Soil	Construction underway
TX	Pantex Plant (USDOE)	Y	Y	Groundwater	Construction complete
WV	Allegany Ballistics Laboratory (USNAVY)+	Y	Y	Soil	Construction underway

* Design underway – refers to a stage before there is a Record of Decision on a final remedy. Early action – indicates that efforts are underway to address contaminated media before the final Record of Decision is in place. Construction underway – indicates that efforts to implement a remedy to address the contaminated media (groundwater or soil), are ongoing. Construction complete – indicates that a remedy has been implemented, but it may be ongoing for some time (in many cases for years).

\+ Describes a site with multiple operable units which often are parcels of land with distinct cleanup plans.

Federal and state agencies have developed best management practices that have contributed to the identification of and reductions to perchlorate levels in the environment. For example, in 2006, the Department of Defense (DOD) issued a handbook to assist DoD facilities in complying with DoD policy governing perchlorate sampling and testing activities for both environmental restoration/cleanup and compliance monitoring programs. The handbook is online at: https://www.denix.osd.mil/cmrmp/ecmr/perchlorate/policy/unassigned/dod-perchlorate-handbook/.

Additionally, the California Department of Toxic Substances Control (DTSC) Best Management Practices Regulations for disposal of perchlorate wastes to prevent release of wastes into the environment became operative on July 1, 2006. More information on the types of perchlorate-containing products that may be subject to these requirements and the perchlorate best management practices is available at: https://dtsc.ca.gov/wp-content/uploads/sites/31/2015/08/HWM_FS_Perchlorate_7-061.pdf.

Perchlorate in Drinking Water due to Use of Sodium Hypochlorite

EPA Actions

Sodium hypochlorite is used for water disinfection and, due to degradation, perchlorate has been detected in hypochlorite solutions. A 2009 study by the American Water Works Association (AWWA) and Water Research Foundation found that perchlorate can be present in hypochlorite solutions and can continue to form with a rate of formation that depends on storage conditions. The study found that to minimize perchlorate formation, hypochlorite solutions should be stored in dark and cool conditions, diluted if possible and used within a few weeks of manufacture.

In response to concerns raised by stakeholders and pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the EPA published an Interim Decision for Calcium, Sodium and Potassium Hypochlorite in March 2018. The Agency requires that advisory best management practices be added to hypochlorite drinking water disinfection product labels to minimize the potential for chlorate and perchlorate formation during storage. These best management practices can be used individually and in combination, and include limited storage time, adequate solution pH range, sunlight exposure avoidance, controlled storage temperature, and dilution.

EPA label amendments for drinking water disinfection products

Summary of Labeling Changes for Hypochlorites in Drinking Water Disinfection End Use Products		
Description	**Labeling Language for Hypochlorites**	**Placement on Label**
For drinking water uses	"The following practices help to minimize degradant formation in drinking water disinfection: • It is recommended to minimize storage time. • It is recommended that the pH solution be in the range of 11-13. • It is recommended to minimize sunlight exposure by storing in opaque containers and / or in a covered area. Solutions should be stored at lower temperatures. Every 5°C reduction in storage temperature will reduce degradant formation by a factor of two.	Precautionary Statements, on applicable labels

	• Dilution significantly reduces degradant formation. For products with higher concentrations, it is recommended to dilute hypochlorite solutions with cool, softened water upon delivery, if practical for the application.”	

Industry Actions

Research by the AWWA and the Water Research Foundation found that hypochlorite concentration, pH, ionic strength, and temperature were major factors impacting perchlorate and chlorate formation in stored hypochlorite solutions at drinking water utilities.

In response, AWWA developed standards and guidance which provide several recommendations to minimize perchlorate formation as a result of hypochlorite decomposition. These recommendations are contained in AWWA's Hypochlorite standard (B300) and include:

1. Dilute stored hypochlorite solutions on delivery.
2. Store hypochlorite solution at lower temperatures (every 5°C reduction reduces perchlorate formation rate by about 2).
3. Control hypochlorite solution within the pH range of 11 to 13.
4. Avoid extended storage times (hypochlorite degrades over time into oxygen, chlorate, and perchlorate; earlier use reduces perchlorate addition because of lower perchlorate concentration and lower disinfectant dosage to satisfy the target chlorine residual).
5. In most U.S. states, chemicals added to drinking water must meet third-party certification for NSF/ANSI/CAN 60: Drinking Water Treatment Chemicals – Health Effects (NSF, 2019). As part of this standard, certification listing, and manufacturer's use instructions or documentation supplied with the product “shall reference the recommended handling and storage practices contained in AWWA B300-Hypochlorites.” (NSF/ANS, 2016, Standard 60, Section 6.3.3.1)
6. In combination, these new EPA labeling requirements, state certification requirements, and industry guidelines recommending best management practices on hypochlorite solutions will minimize the potential for perchlorate formation in systems utilizing hypochlorite products for drinking water disinfection purposes.

CONCLUSION

The EPA re-evaluated the available data on the frequency and level of perchlorate occurrence in public water systems. The EPA has compared this information to the lowest potential Maximum Contaminant

Level Goal under consideration by the Agency in the June 19, 2019 proposal. The EPA concludes that there is infrequent occurrence of perchlorate at the levels of public health concern. In addition, studies show that perchlorate occurrence in the environment has decreased over time, due to several mitigation actions taken by the EPA and others.

REFERENCES

American Water Works Association (AWWA) 2008. National Cost Implications of a Potential Perchlorate Regulation. July.

Arizona Department of Environmental Quality (ADEQ), Arizona Department of Health Services (ADHS), Arizona Department of Water Resources (ADWR), and Arizona Department of Agriculture (ADOA). 2004. Perchlorate in Arizona: Occurrence Study of 2004. December 2004. Available on the Internet at: http://azmemory.azlibrary.gov/cdm/ref/collection/statepubs/id/604.

City of Phoenix Water Services Department. 2012. Q&A: Perchlorate. Available on the Internet at: https://www.phoenix.gov/waterservicessite/Documents/wsdfaqperchlorate032612.pdf

Luis et al. 2019. Luis, S.J., E.A. Miesner, C.L. Enslin, and K. Heidecorn. 2019. Review of perchlorate occurrence in large public drinking water systems in the United States of America. Water Supply 19(3): 681-694. Retrieved from https://pdfs.semanticscholar.org/c508/2c66bf61d7e41c700912413e66130c43aaed.pdf.

Nevada Division of Environmental Protection (NDEP). 2011. Overview of Las Vegas Valley Perchlorate Remediation Efforts. (August 2013 Presentation for USEPA.) Version prepared to the Lake Mead Ecosystem Monitoring Workgroup (August 2013). Available on the Internet at: https://ca-nv-awwa.org/CANV/downloads/2015/afc15presentations/OVERVIEWOfLASVEGAS.pdf.

Message

From: Bertrand, Charlotte [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F044D768E05842E1B75321FF6010E1B8-BERTRAND, CHARLOTTE]
Sent: 5/21/2020 8:21:48 PM
To: Evalenko, Sandy [Evalenko.Sandy@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]
Subject: FW: Charlotte - for review/signature - Perchlorate FRN to OP for Interagency Review
Attachments: EO12866_SDWA NPDWR 2040-AF28 FRN Perchlorate Rule 20200521.docx; Perchlorate Action Memo 5-19-20.docx; Perchlorate Transmittal Memo AA to OP for OMB Review.pdf

Importance: High

Hi! Here is the signed memo. Thanks for pulling it together for me, Charlotte

---

From: Aguirre, Janita <Aguirre.Janita@epa.gov>
Sent: Thursday, May 21, 2020 3:10 PM
To: Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Ross, David P <ross.davidp@epa.gov>; Braschayko, Kelley <braschayko.kelley@epa.gov>
Subject: Charlotte - for review/signature - Perchlorate FRN to OP for Interagency Review
Importance: High

Hi Charlotte,

Please see the electronic blue folder for the Notice of Final Action on Perchlorate to go to OP to be submitted to OMB for interagency review. I spoke with Dave and he has delegated package approval/transmittal memo signature to you. When you are ready to approve, please sign the transmittal memo (attachment 1). Please let me know if you find any edits to the memo or the package. Once signed, please send it back to me, and Sandy will move it to the next step.

- For attachment 1, your e-signature in PDF will look something like this:

SHARON HAMER

Digitally signed by SHARON HAMER
Date: 2020.03.12 17:21:45 -04'00'

Attachments

1. SIGN: Transmittal memo for your signature
2. Draft Perchlorate FRN to be sent to OMB
3. Draft Action Memo (will be kept in draft until time for final FRN signature).
4. OCG Concurrence emails – see below my signature block

Thank you,
Janita

Janita Aguirre – Special Assistant to David Ross and Anna Wildeman
U.S. Environmental Protection Agency | Office of Water | Office of the Assistant Administrator
Phone: **(202) 566-1149** | Email: aguirre.janita@epa.gov

From: Parikh, Pooja <Parikh.Pooja@epa.gov>
Sent: Thursday, May 21, 2020 12:04 PM
To: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Cc: Wehling, Carrie <Wehling.Carrie@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Request for Concurrence - Revised Perchlorate FRN

Sam,

Per our discussion, I have reviewed the redlined version of all of the changes to the FRN since the FAR version. I confirmed that all of OGC's comments on the FAR version have been sufficiently addressed – and only had a couple of minor additional edits – please see attached (my edits are marked with comment bubbles). With these edits, the FRN is ready to move forward. Thanks.

Pooja

Pooja S. Parikh
Attorney- Advisor
U.S. Environmental Protection Agency
Office of General Counsel, Water Law Office
Phone: 202 564-0839
Email: parikh.pooja@epa.gov

From: Parikh, Pooja <Parikh.Pooja@epa.gov>
Sent: Thursday, May 07, 2020 9:52 AM
To: Evalenko, Sandy <Evalenko.Sandy@epa.gov>
Cc: Wehling, Carrie <Wehling.Carrie@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: Perchlorate FRN -- OGC concurs with comment

On behalf of the General Counsel, I am providing OGC's concurrence on the Federal Register Notice referenced in the email below, subject to the attached comments. I will be representing OGC at the FAR meeting. Please let me know if you have any questions or require additional information. Thank you.

Pooja

Pooja S. Parikh
Attorney- Advisor
U.S. Environmental Protection Agency
Office of General Counsel, Water Law Office
Phone: 202 564-0839
Email: parikh.pooja@epa.gov

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF WATER

MEMORANDUM

SUBJECT: Transmittal of the Notice of Final Action on Perchlorate (Tier 1 Action; SAN 5555; RIN 2040-AF28) to the Office of Management and Budget for Executive Order 12866 Review

FROM: Charlotte Bertrand, Deputy Assistant Administrator CHARLOTTE BERTRAND Digitally signed by CHARLOTTE BERTRAND Date: 2020.05.21 16:19:29 -04'00'

TO: Brittany Bolen, Associate Administrator
Office of Policy

Attached for the Office of Policy's review and transmittal to the Office of Management and Budget (OMB) for Executive Order 12866 interagency review is a *Federal Register* notice titled: "Notice of Final Action on Perchlorate."

On February 11, 2011, the U.S. Environmental Protection Agency (EPA or Agency) published a determination to regulate perchlorate in drinking water (76 FR 7762). On June 26, 2019 (84 FR 30524), the EPA published the proposed National Primary Drinking Water Regulations for Perchlorate and requested public comments on multiple alternative actions, including withdrawing the 2011 determination to regulate perchlorate. The EPA received approximately 1,500 comments on the proposed rule. In the attached notice, the EPA is withdrawing the 2011 Regulatory Determination and is making a final determination not to regulate perchlorate based on the Agency's consideration of public comments and the best available science.

I request that the Office of Policy seek an expedited interagency review in accordance with Executive Order 12866 to meet a consent decree deadline for signature of the final action by June 19, 2020.

If you have any questions, please contact me or have your staff contact Samuel Hernandez at 202-564-1735.

Attachments

Message

From:	Bertrand, Charlotte [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F044D768E05842E1B75321FF6010E1B8-BERTRAND, CHARLOTTE]
Sent:	5/18/2020 9:28:54 PM
To:	McLain, Jennifer L. [Mclain.Jennifer@epa.gov]
CC:	Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Braschayko, Kelley [braschayko.kelley@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]
Subject:	RE: Notice of Final Action on Perchlorate
Attachments:	Perchlorate Action Memo 5-18-20.cb.docx; Draft Perchlorate Final Action FRN 5-18-20 v1 Redline.cb.docx

Thanks – couple of bubble box questions and then I had one redline edit I added to the Notice.

From: McLain, Jennifer L. <McLain.Jennifer@epa.gov>
Sent: Monday, May 18, 2020 3:01 PM
To: Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Braschayko, Kelley <braschayko.kelley@epa.gov>; Tiago, Joseph <Tiago.Joseph@epa.gov>; Aguirre, Janita <Aguirre.Janita@epa.gov>
Subject: FW: Notice of Final Action on Perchlorate

Charlotte – as agreed, I'm sending you the draft final perchlorate FRN for review. The redline includes the changes made since the FAR. I'm also including the draft Action Memo. Please let us know if your preference is to have these submitted to OW through CMS now or after you have reviewed. Let me know if you want to talk.

Jennifer

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Monday, May 18, 2020 2:48 PM
To: McLain, Jennifer L. <McLain.Jennifer@epa.gov>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Tiago, Joseph <Tiago.Joseph@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: FW: Notice of Final Action on Perchlorate

Jennifer:

Attached for transmission to OW are revised versions of the FRN for the Perchlorate Final Action. There is both a clean and track changes version that includes edits made since initiating FAR (including the edits you asked for on Saturday and adding 3 more SAB recommendations to page 14 that were in the proposal but were not included in the draft we provided you on Friday). Also please find clean version of the transmittal memo from you to Dave Ross and the Action memo incorporating your edits.

Please note that there is also a redline version of the Action Memo for you to see the responses to your comments on the document. I do not recommend transmitting that memo to OW.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Sent: Monday, May 18, 2020 2:18 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Notice of Final Action on Perchlorate

Hi Eric,

Attached are the revised Redline and Clean versions of the Perchlorate FR Notice. Once we are ready for OP's submittal to OMB let me know and I will provide a version that adheres to OP's file name formatting guidelines.

Thanks
Sam
==
Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Monday, May 18, 2020 1:14 PM
To: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Notice of Final Action on Perchlorate

Sam

1. Change the title please. This was requested by OGC at Sr. Leadership levels.
2. Provide the same level of detail on the SAB recommendations as was included in the proposal.
3. I don't think the HRRCA text is necessary and do not want to add it at this stage since there are OGC edits that already make this clear.

Eric

From: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Sent: Monday, May 18, 2020 12:41 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Notice of Final Action on Perchlorate

Hi Eric,

Here is a revised Redline of the document (from FAR). We had a few questions/issues for your consideration about the attached file. Specifically:,

1- Page #1, Notice Tittle: We did not accept the edits to the notice tittle. Because, the tittle of the notice was specifically crafted by OGC to capture the multiple actions EPA is taking. Suggest consulting with OGC before modifying this tittle.
2- Page #14, SAB Recommendations: SAB provided 4 main recommendations in 2013 but we only listed the first recommendation. Please advise if we should list all 4 recommendations here or not.

3- Page #26, Missing HRRCA Text: This language was offered by TAB in its 5-13-20 version of the draft FRN, but it did not show up in the version provided by OGWDW with Eric's & Jennifer's comments. We have inserted the language here for the reviewer's consideration. Please advise if we should keep it.

Once you provide your feedback, I will modify the redline version and also provide a Clean copy for transmittal.

Thanks
Sam
==

Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Monday, May 18, 2020 8:42 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Cc: McLain, Jennifer L. <McLain.Jennifer@epa.gov>; Tiago, Joseph <Tiago.Joseph@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
Subject: FW: Notice of Final Action on Perchlorate

Lisa and Sam
Attached are Jennifer's comments and edits on the draft FRN. I have responded to her questions in the attached and made some additional edits. Can you please get a revised clean version and another redline version that compares this document and the version that was distributed to FAR?
Thanks for your work on this.
Eric

From: McLain, Jennifer L. <McLain.Jennifer@epa.gov>
Sent: Saturday, May 16, 2020 11:39 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Notice of Final Action on Perchlorate

Looks very good. See p. 6 for my only concern w/the revisions.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, May 15, 2020 5:03 PM
To: McLain, Jennifer L. <McLain.Jennifer@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Tiago, Joseph <Tiago.Joseph@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
Subject: Notice of Final Action on Perchlorate

Jennifer

Attached for your approval and transmittal to the Office of Water for their approval and transmittal to the Office Policy for initiation of interagency review is a *Federal Register* notice titled: "Notice of Final Action on Perchlorate." Also attached for your review are a draft transmittal memo from you to the Assistant

Administrator of Water, a draft Action Memorandum and a track changes version of the FR notice that denotes the changes made as a result of Final Agency Review.

On February 11, 2011, the EPA published a determination to regulate perchlorate in drinking water (76 FR 7762). On June 26, 2019 (84 FR 30524), the EPA published the proposed National Primary Drinking Water Regulation for Perchlorate and requested public comments on multiple alternative actions, including withdrawing the 2011 determination to regulate perchlorate. The EPA received approximately 1,500 comments on the proposed rule. In the attached notice, the EPA is withdrawing the 2011 Regulatory Determination and is making a final determination not to regulate perchlorate based on the Agency's consideration of public comments and the best available information.

I recommend that you approve and transmit the attached notice to the Office of Water for their review, approval and transmission to the Office of Policy to initiate interagency review in accordance with Executive Order 12866. If you need additional information or have questions pertaining to any aspect of this notice, please call me or have your staff contact Samuel Hernandez at 202-564-1735.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

*** Deliberative Draft – Do Not Cite, Quote, or Release During Review***

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[EPA-HQ-OW-2018-0780, EPA–HQ–OW–2008–0692, EPA–HQ–OW– 2009–0297; FRL-XXXX-XX-OW]

RIN 2040-AF28

Drinking Water: Notice of ~~Withdrawal of the 2011 Perchlorate Regulatory Determination and Publication of the~~ Final Action~~Regulatory Determination~~ on Perchlorate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of Regulatory Determination and Final Regulatory Determination.

Commented [BC1]: Will this show up publicly in ROCIS?

SUMMARY: The Environmental Protection Agency (EPA) is announcing its withdrawal of the 2011 determination to regulate perchlorate in accordance with the Safe Drinking Water Act (SDWA). On February 11, 2011 ~~(76 FR 7762),~~, the ~~Agency~~EPA published a *Federal Register* notice in which the ~~EPA~~Agency determined that perchlorate met the SDWA's criteria for regulating a contaminant. On June 26, 2019 ~~(84 FR 30524),~~, the EPA published a proposed national primary drinking water regulation (NPDWR) for perchlorate and requested public comments on multiple alternative regulatory actions, including the alternative of withdrawing the 2011 regulatory determination for perchlorate. The ~~Agency~~EPA received approximately 1,500 comments on the proposed rule. The EPA has considered these public comments and based on the best available information the Agency is withdrawing the 2011 regulatory determination and

is making a final determination to not ~~to~~ regulate perchlorate. The ~~Agency~~EPA has determined that perchlorate does not occur with a frequency and at levels of public health concern, and that regulation of perchlorate does not present a meaningful opportunity for health risk reduction for persons served by public water systems.

DATES: For purposes of judicial review, the regulatory determination in this document is issued as of *[insert date of publication in the* Federal Register*]***.**

FOR FURTHER INFORMATION CONTACT: Samuel Hernandez, Office of Ground Water and Drinking Water, Standards and Risk Management Division (Mail Code 4607M), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone number: (202) 564-1735; email address: hernandez.samuel@epa.gov.

SUPPLEMENTARY INFORMATION: This notice is organized as follows:

I. General Information

A. Does This Action Apply to Me?

This action will not impose any requirements on anyone. Instead, this action notifies interested parties of the EPA's withdrawal of the 2011 regulatory determination for perchlorate and the final regulatory determination to not regulate perchlorate ~~based on new information.~~.

This notice also provides a summary of the major comments received on the June 26, 2019 (84 FR 30524) proposed NPDWR for perchlorate.

B. How can I get Copies of this Document and other Related Information?

The EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2018–0780. Publicly available docket materials are available electronically at [HYPERLINK "http://www.regulations.gov/docket?D=EPA-HQ-OW-2018-0780"].

II. Background

A. What is Perchlorate?

Perchlorate is a negatively charged inorganic ion that is comprised of one chlorine atom bound to four oxygen atoms (ClO_4-), which is highly stable and mobile in the aqueous environment. Perchlorate comes from both natural and manmade sources. It is formed naturally via atmospheric processes and can be found within mineral deposits in certain geographical areas. It is also produced in the United States, and the most common compounds include ammonium perchlorate and potassium perchlorate used primarily as oxidizers in solid fuels to power rockets, missiles, and fireworks. Perchlorate can also result from the degradation of hypochlorite solutions used for water disinfection. The degradation into perchlorate occurs when hypochlorite solutions are improperly stored and handled. For the general population, most perchlorate exposure is through the ingestion of contaminated food or drinking water. At certain levels, perchlorate can prevent the thyroid gland from getting enough iodine, which can affect thyroid hormone production. For pregnant women with low iodine levels, sufficient changes in thyroid hormone levels may cause changes in the child's brain development. For infants, changes to thyroid hormone function can also impact brain development.

B. What is the purpose of this action?

The purpose of ~~today's~~this action is to publish the EPA's notice to withdraw the 2011 regulatory determination and issue a final determination to not regulate perchlorate in drinking water. This notice presents the EPA's basis for this withdrawal and final regulatory determination, and the EPA's response to key issues raised by commenters in response to the June 26, 2019 (84 FR 30524) proposed rule (referred to hereinafter as "the 2019 proposal").

C. What is the EPA's statutory authority for this action?

The SDWA sets forth three criteria that must be met for the EPA to issue a maximum contaminant level goal (MCLG) and promulgate a national primary drinking water regulation (NPDWR). Specifically, the Administrator must determine that (1) "the contaminant may have an adverse effect on the health of persons"; (2) "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern"; and (3) "in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by ~~the~~ public water systems" (SDWA 1412(b)(1)(A)).

The EPA has determined, based on ~~new~~ data and analysis since the issuance of the 2011 regulatory determination, that perchlorate does not in fact meet the statutorily-prescribed criteria for regulation. As described in Sections III & VI of the 2019 proposal, the ~~new~~ data and analysis in the record indicate that perchlorate does not occur in public water systems with a frequency and at levels of public health concern. Specifically, the ~~new~~ peer-reviewed health effects analysis ~~yields a health based proposed MCLG and proposed alternative MCLGs for~~ indicates that the concentration of perchlorate ~~that are higher concentrations in drinking water (18 – 90 µg/L) than the concentrations that the EPA considered to be~~representing the proposal MCLG alternatives for levels of public health concern ~~in~~(18-90 µg/L) is higher than the concentration considered in issuance of the ~~analysis for the~~ 2011 regulatory determination ~~to regulate in 2011~~ (1-47 µg/L) (USEPA, 2019a). In addition, based on an evaluation of the nationally representative UCMR 1 systems, the updated occurrence analysis shows that the frequency of occurrence of perchlorate in public water systems at levels exceeding any of the alternative proposed MCLGs ~~(0.38% - 0.02%)~~ is significantly lower (0.38% - 0.02%) than the frequency considered in the analysis for the 2011 regulatory determination (4% - 0.39%) (USEPA, 2019b). The EPA estimates that, even at the most stringent regulatory level considered in the 2019 proposal~~,~~ (18 µg/L), not more than 15 systems (0.03% of all water systems in the U.S.) would need to take action to reduce levels of perchlorate. Based on this information, the EPA determines that perchlorate does not occur in public water systems "with a frequency…of public health concern" and thus does not meet the second criterion of the three required for regulation under the SDWA. In addition, while the third criterion is "in the sole judgement of the Administrator," the low occurrence provides ample support for the EPA's conclusion that the regulation of perchlorate does not present a "meaningful opportunity for health risk reduction for persons served by public water systems," within the meaning of 1412(b)(1)(A)(iii). Accordingly, because perchlorate no longer meets the statutory criteria for regulation, the EPA does not have the authority to issue a MCLG or promulgate a NPDWR for perchlorate.

The EPA's decision to withdraw the regulatory determination is supported by the legislative history underlying the 1996 amendments to the SDWA, which repealed the ~~blanket rule requiring~~statutory requirement for the EPA to regulate an additional 25 contaminants every 3 years and replaced it with the current requirement for the EPA to determine whether regulation is warranted for ~~5~~five contaminants every ~~5~~five years. In describing the need for such amendment, the legislative history points to the view expressed at the Committee Hearing that "the current law is a one-size-fits-all program. It forces our water quality experts to spend scarce resources searching for dangers that often do not exist rather than identifying and removing real health risks from our drinking water" (S. Rep. 104-169 (1995) at 12). This amendment reflected Congress' clear intent that the EPA prioritize actual health risks in determining whether to regulate any particular contaminant. *See id* at 12 (noting that the amendment "repeals the requirement that the EPA regulate an additional 25 contaminants every 3 years replacing it with a new selection process that gives the EPA the discretion to identify contaminants that warrant regulation in the future").

The EPA's decision to withdraw the regulatory determination is also consistent with Congress' direction to prioritize the SDWA decisions based on the best available public health information. *See* 1412(b)(1)(B)(ii)(II) (findings supporting a determination to regulate "shall be based on the best available public health information"); 1412(b)(2)(A) (requiring that the EPA use "the best available, peer-reviewed science and supporting studies…" in carrying out any actions under this section). Although the EPA determined in 2011 that perchlorate met the criteria for regulation, new data and analysis developed by the ~~EPA~~Agency as part of the 2019 proposal demonstrate that the occurrence and health effects information used as the basis for the 2011 determination no longer constitute "best available information," are no longer accurate and no longer support the Agency's prioritization of perchlorate for regulation. Accordingly, not only is EPA not authorized to issue a MCLG or promulgate a NPDWR for perchlorate, but it would not be in the public interest to do so.

The EPA recognizes that the Act does not include a provision explicitly authorizing withdrawal of a regulatory determination. However, such authority is inherent in the authority to issue a regulatory determination under 1412(b)(1)(B)(ii)(II), particularly given the requirement that such determination be based on the "best available public health information," as discussed above. Accordingly, the EPA must have the inherent authority to withdraw a regulatory determination if the underlying information changes between regulatory determination and promulgation. ~~Particularly~~ In light of its concern that the EPA focus new contaminant ~~regulation~~regulations on priority health concerns, Congress could not have intended that the EPA's regulatory decision-making be hamstrung by older data when newer, more accurate scientific and public health data are available, especially when those data demonstrate that regulation of a new contaminant would not ~~be~~present a meaningful opportunity for health risk reduction.

Moreover, the EPA notes that the statute specifically provides that a decision to not ~~to~~ regulate a contaminant is a final Agency action subject to judicial review. The SDWA, section 1412(b)(1)(B)(ii)(IV). ~~Congress'~~Congress could have – but did not – specify the same with respect to determinations to regulate. Congress also did not explicitly prohibit the EPA from withdrawing or modifying a regulatory determination. Congress' silence with respect to ~~regulatory~~ determinations to regulate suggests that Congress intended that such ~~determinations are~~a determination is not ~~in fact~~itself a final agency ~~actions subject to judicial review~~action, but rather, a preliminary ~~decisions to regulate~~step in a decision-making process culminating in a NPDWR and thus, subject to reconsideration based on new data and analysis considered during the 36 month promulgation process specified in the statute. Accordingly, reconsideration of this preliminary finding – and withdrawal of the determination based on subsequent analysis mandated for NPDWR development – is fully consistent with the statutory decision-making framework.

D. Statutory Framework and Perchlorate Regulatory History

Section 1412(b)(1)(B)(i) of the SDWA requires the EPA to publish every five years a Contaminant Candidate List (CCL). The CCL is a list of drinking water contaminants that are known or anticipated to occur in public water systems and are not currently subject to federal drinking water regulations. The EPA uses the CCL to identify priority contaminants for regulatory decision-making and information collection. Contaminants listed on the CCL may require future regulation under the SDWA. The EPA included perchlorate on the first, second, and third CCLs published in 1998 (63 FR 10274), 2005 (70 FR 9071), and 2009 (74 FR 51850).

The ~~Agency~~ EPA collects data on the CCL contaminants to better understand their potential health effects and to determine the levels at which they occur in public water systems. The SDWA, section 1412(b)(1)(B)(ii) requires that, every five years, the EPA, after consideration of public comment, issue a determination of whether or not to regulate at least five contaminants on each CCL. For any contaminant that the EPA determines meets the SDWA criteria for regulation, under the SDWA, section 1412(b)(1)(E), the EPA must propose a NPDWR within two years and promulgate a final regulation within 18 months of the proposal (which may be extended by 9 additional months).

As part of its responsibilities under the SDWA, the EPA implements section 1445(a)(2), "Monitoring Program for Unregulated Contaminants." This section requires that once every five years, the EPA issue a list of no more than 30 unregulated contaminants to be monitored by public water systems. This monitoring is implemented through the Unregulated Contaminant Monitoring Rule (UCMR), which collects data from community water systems ~~(CWS)~~ and non-transient, non-community water systems ~~(NTNCWS).~~. The first four UCMRs collected data from a census of large water systems (serving more than 10,000 people) and from a statistically representative sample of small water systems. On September 17, 1999, the EPA published its first UCMR (64 FR 50556)), which required all large systems and a representative sample of small systems to monitor for perchlorate and 25 other contaminants (USEPA, 1999). Water system monitoring data for perchlorate was collected from 2001 to 2005.

The EPA and other federal agencies asked the National Research Council (NRC) to evaluate the health implications of perchlorate ingestion. In its 2005 report, the NRC concluded that perchlorate exposure inhibits the transport of iodide[1] into the thyroid by a protein molecule known as the sodium/iodide symporter (NIS), which may lead to decreases in two thyroid hormones, thyroxine (T3) and triiodothyronine (T4), and increases in thyroid-stimulating hormone (TSH) [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a1mn5hjprkt","properties":{"formattedCitation":"(National Research Council (NRC), 2005b)","plainCitation":"(National Research Council (NRC), 2005b)","noteIndex":0},"citationItems":[{"id":350,"uris":["http://zotero.org/groups/945096/items/TN6HMC9D"],"uri":["http://zotero.org/groups/945096/items/TN6HMC9D"],"itemData":{"id":350,"type":"book","title":"Health Implications of Perchlorate Ingestion","publisher":"National Academies Press","publisher-place":"Washington, DC","event-place":"Washington, DC","author":[{"literal":"National Research Council (NRC)"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Additionally, the NRC concluded that the

[1] For the purposes of this notice, “iodine” will be used to refer to dietary intake before entering the body. Once in the body, “iodide” will be used to refer to the ionic form.

most sensitive population to perchlorate exposure are "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" (p. 178). The EPA established a reference dose (RfD) consistent with the NRC's recommended RfD of 0.7 μg/kg/day for perchlorate. The reference dose is an estimate of a human's daily exposure to perchlorate that is likely to be without an appreciable risk of adverse effects. This RfD was based on a study [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a3u94lt6me","properties":{"formattedCitation":"(Greer, Goodman, Pleus, & Greer, 2002)","plainCitation":"(Greer, Goodman, Pleus, & Greer, 2002)","noteIndex":0},"citationItems":[{"id":387,"uris":["http://zotero.org/groups/945096/items/6AKUNIX6"],"uri":["http://zotero.org/groups/945096/items/6AKUNIX6"],"itemData":{"id":387,"type":"article-journal","title":"Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans","container-title":"Environmental Health Perspectives","page":"927","volume":"110","issue":"9","author":[{"family":"Greer","given":"Monte A."},{"family":"Goodman","given":"Gay"},{"family":"Pleus","given":"Richard C."},{"family":"Greer","given":"Susan E."}],"issued":{"date-parts":[["2002"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] of perchlorate's inhibition of radioactive iodine uptake in healthy adults and the application of an uncertainty factor of 10 for intraspecies variability [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"0oHz805e","properties":{"formattedCitation":"(USEPA, 2005b)","plainCitation":"(USEPA, 2005b)","noteIndex":0},"citationItems":[{"id":980,"uris":["http://zotero.org/groups/945096/items/LHANJBR6"],"uri":["http://zotero.org/groups/945096/items/LHANJBR6"],"itemData":{"id":980,"type":"article","title":"Integrated Risk Information System (IRIS) Chemical Assessment Summary: Perchlorate (ClO4-) and Perchlorate Salts","publisher":"USEPA National Center for Environmental Assessment","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

In October 2008, the EPA published a preliminary regulatory determination to not ~~to~~ regulate perchlorate in drinking water and requested public comment (73 FR 60262). In that preliminary determination, the EPA found that perchlorate did not occur with a frequency and at levels of public health concern and that development of a regulation did not present a meaningful opportunity for health risk reduction for persons served by public water systems. The EPA derived and used a Health Reference Level (HRL) of 15 µg/L based on the RfD of 0.7 µg/kg/day and body weight and exposure information for pregnant women in making this conclusion [ADDIN ZOTERO_ITEM CSL_CITATION

{"citationID":"FZ6WMtAv","properties":{"formattedCitation":"(USEPA, 2008a)","plainCitation":"(USEPA, 2008a)","noteIndex":0},"citationItems":[{"id":934,"uris":["http://zotero.org/groups/945096/items/HBX88QM9"],"uri":["http://zotero.org/groups/945096/items/HBX88QM9"],"itemData":{"id":

934,"type":"article-journal","title":"Drinking water: Preliminary regulatory determination on perchlorate","container-title":"Federal Register","volume":"73","issue":"198","abstract":"SUMMARY: This action presents EPA's preliminary regulatory determination for perchlorate in accordance with the Safe Drinking Water Act (SDWA). The Agency has determined that a national primary drinking water regulation (NPDWR) for perchlorate would not present \"a meaningful opportunity for health risk reduction for persons served by public water systems." The SDWA requires EPA to make determinations every five years of whether to regulate at least five contaminants on the Contaminant Candidate List (CCL). EPA included perchlorate on the first and second CCLs that were published in the Federal Register on March 2, 1998 and February 24, 2005. Most recently, EPA presented final regulatory determinations regarding 11 contaminants on the second CCL in a notice published in the Federal Register on July 30, 2008. In today's action, EPA presents supporting rationale and requests public comment on its preliminary regulatory determination for perchlorate. EPA will make a final regulatory determination for perchlorate after considering comments and information provided in the 30-day comment period following this notice. EPA plans to publish a health advisory for perchlorate at the time the Agency publishes its final regulatory determination to provide State and local public health officials with technical information that they may use in addressing local contamination.","ISSN":"ISSN 0097-6326 EISSN 2167-2520","shortTitle":"Federal Register","journalAbbreviation":"Fed. Reg.","language":"English","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2008"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Using the UCMR 1 occurrence data, the EPA estimated that less than 1% of drinking water systems (serving approximately 1 million people) had perchlorate levels above the HRL of 15 µg/L. Based on this information the ~~Agency~~EPA found that perchlorate did not occur ~~frequently~~at a frequency and at levels of public health concern. The EPA also determined there was not a meaningful opportunity for a NPDWR for perchlorate to reduce health risks.

In August 2009, the EPA published a supplemental request for comment with new analysis that derived potential alternative Health Reference Levels (HRLs) for 14 life stages, including infants and children. The analysis used the RfD of 0.7 µg/kg/day and life stage-specific bodyweight and exposure information, resulting in comparable perchlorate concentrations in drinking water, based on life stage, of between 1 µg/l to 47 µg/l (74 FR 41883; USEPA, 2009).

~~On~~In February 11, 2011, the EPA published its determination to regulate perchlorate (76 FR 7762; USEPA, 2011) after careful consideration of public comments on the October 2008 and August 2009 notices. The ~~Agency~~EPA found at that time that perchlorate may have an adverse effect on the health of persons, it is known to occur in public drinking water systems with a frequency and at levels that present a public health concern, and regulation of perchlorate presented a meaningful opportunity for health risk reduction for persons served by public water systems. The ~~Agency~~EPA stated then that: "*Based on the data in Table 1 and the range of potential alternative HRLs, EPA has determined that perchlorate is known to occur or there is a* *substantial likelihood that it will occur with a frequency and at levels of public health concern.*"(USEPA, 2011, p. 7765). The EPA found that as many as 16 million people could potentially be exposed to perchlorate at levels of concern, up from 1 million people originally estimated in the 2008 notice.

As a result of the determination, and as required by the SDWA, section 1412(b)(1)(E), the EPA initiated the process to develop a MCLG and a NPDWR for perchlorate.

In September 2012, the U.S. Chamber of Commerce (the Chamber) submitted to the EPA a Request for Correction under the Information Quality Act regarding the EPA's regulatory determination. In the request, the Chamber claimed that the UCMR 1 data used in the EPA's occurrence analysis did not comply with data quality guidelines and were not representative of current conditions. In response to this request, the EPA reassessed the data and removed certain source water samples that could be paired with appropriate follow-up samples located at the entry point to the distribution system. The EPA also updated the UCMR 1 data in the analysis for systems in California and Massachusetts, using state compliance data to reflect current occurrence conditions after state regulatory limits for perchlorate were implemented.

As required by section 1412(d) of the SDWA, as part of the NPDWR development process, the EPA requested comments from the Science Advisory Board (SAB) in 2012, seeking guidance on how best to consider and interpret the life stage information, the epidemiologic and biomonitoring data since the NRC report, physiologically-based pharmacokinetic (PBPK) analyses, and the totality of perchlorate health information to derive an MCLG for perchlorate. In May 2013, the SAB recommended that the EPA:

- derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling based upon its mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters;
- expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;
- utilize a mode-of-action framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition—to thyroid hormone changes—and finally to neurodevelopmental impacts; and
- ‘‘Extend the [BBDR] model expeditiously to . . . provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages’’(SAB for the U.S. EPA, 2013, p. 19).

To address the SAB recommendations, the EPA revised an existing PBPK/PD model that describes the dynamics of perchlorate, iodide, and thyroid hormones in a woman during the third trimester of pregnancy (Lumen, Mattie, & Fisher, 2013; USEPA, 2009b). The EPA also created its own Biologically Based Dose Response (BBDR) models that included the additional sensitive life stages identified by the SAB, *i.e.*, breast- and bottle-fed neonates and infants (SAB for the U.S. EPA, 2013, p. 19).

To determine whether the Agency had implemented the SAB recommendations for modeling thyroid hormone changes, the EPA convened an independent peer review panel to evaluate the BBDR models in January 2017 (External Peer Reviewers for USEPA, 2017). The EPA considered the recommendations from the 2017 peer review and made necessary model revisions to increase the scientific rigor of the model and the modeling results.

The EPA convened a second independent peer review panel in January 2018 to evaluate the revisions to the BBDR model. The EPA also presented several approaches to link the thyroid hormone changes in a pregnant mother predicted by the BBDR model to neurodevelopmental effects using evidence from the epidemiological literature (External Peer Review for U.S. EPA, 2018).

In response to a lawsuit brought to enforce the deadlines in the SDWA, section 1412(b)(1)(E), on October 18, 2016, the U.S. District Court for the Southern District of New York entered a consent decree, requiring the EPA to sign for publication a proposal for a MCLG and NPDWR for perchlorate in drinking water no later than October 31, 2018, and to sign for publication a final MCLG and NPDWR for perchlorate in drinking water no later than December 19, 2019. The deadline for the EPA to propose a MCLG and NPDWR for perchlorate in drinking water was later extended to May 28, 2019, and the date for signature of a final MCLG and

NPDWR was extended to be no later than June 19, 2020. The consent decree is available in the docket for ~~today's~~this action.

In compliance with the deadline established in the consent decree, on May 23, 2019, the EPA Administrator signed a proposed rulemaking notice seeking public comment on a range of options regarding the regulation of perchlorate in public drinking water systems. The proposed rulemaking notice was published in the *Federal Register* on June 26, 2019. 84 Fed. Reg. 30524. The EPA proposed a NPDWR for perchlorate with ~~a~~an MCL and MCLG of 56 µg/L. The proposed MCLG of 56 µg/L was based on avoiding a 2 point IQ decrement associated with exposure to perchlorate in drinking water during the most sensitive life stage (the fetus) within a specific segment of the population (iodine deficient pregnant women).

The ~~Agency~~EPA also requested comment on two alternative MCL/MCLG values of 18 µg/L and 90 µg/L~~, respectively.~~. These alternatives were based upon avoiding 1 point and 3 point IQ decrements respectively, associated with perchlorate exposure. Additionally, the EPA requested comment on whether the 2011 regulatory determination should be withdrawn, based on new information including updated occurrence data on perchlorate in drinking water and new analysis of the concentration of perchlorate in drinking water that represents a level of health concern.

III. Withdrawal of the 2011 Regulatory Determination and Final Determination to Not Regulate Perchlorate

In determining whether to regulate a particular contaminant, the EPA must follow the criteria mandated by the 1996 SDWA Amendments. Specifically, in order to issue a MCLG and NPDWR for perchlorate, the EPA must determine that perchlorate "may have an adverse effect on the health of persons," that perchlorate occurs at "a frequency and at levels of public health concern" in public water systems, and that regulation of perchlorate in drinking water systems "presents a meaningful opportunity for health risk ~~reductions~~reduction for persons served by public water systems." The SDWA, section 1412(b)(1)(A). In preparing the 2019 proposal for perchlorate, the EPA updated and improved information on the levels of public health concern and the frequency and levels of perchlorate in public water systems. The following is the EPA's reassessment of the regulatory determination criteria applied to the ~~improved~~best available health science and occurrence data ~~available~~ for perchlorate.

A. May perchlorate have an adverse effect on the health of persons?

Yes, perchlorate may have adverse health effects. The perchlorate anion is biologically significant specifically with respect to the functioning of the thyroid gland. Perchlorate can interfere with the normal functioning of the thyroid gland by inhibiting the transport of iodide into the thyroid, resulting in a deficiency of iodide in the thyroid. Perchlorate inhibits (or blocks) iodide transport into the thyroid by chemically competing with iodide, which has a similar shape and electric charge. The transfer of iodide from the blood into the thyroid is an essential step in the synthesis of thyroid hormones. Thyroid hormones play an important role in the regulation of metabolic processes throughout the body and are also critical to developing fetuses and infants, especially for brain development. Because the developing fetus depends on an adequate supply of maternal thyroid hormones for its central nervous system development during the first and second trimester of pregnancy, iodide uptake inhibition from perchlorate exposure has been identified as a concern in connection with increasing risk of neurodevelopmental impairment in fetuses of pregnant women with low dietary iodine. Poor iodide uptake and subsequent impairment of the thyroid function in pregnant and lactating women have been linked to delayed development and decreased learning capability in their infants and children (NRC, 2005). Therefore, the EPA continues to find that perchlorate may have an adverse effect on the health of persons.

B. Is perchlorate known to occur or is there a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern?

The EPA has determined that perchlorate does not occur ~~at~~with a frequency and at levels of public health concern in public water systems. The EPA has made this determination by comparing the best available data on the occurrence of perchlorate in public water systems to potential MCLGs for perchlorate.

In past regulatory determinations, the EPA has identified HRLs as benchmarks against which the EPA compares the concentration of a contaminant found in public water systems to determine if it ~~is~~occurs at levels of public health concern. For the 2011 regulatory determination the EPA identified potential HRLs values ranging from 1 to 47 μg/L for 14 different life-_stages.

These HRLs were not final decisions about the level of perchlorate in drinking water that is ~~necessary to protect any particular population.~~ without adverse effects. For the 2019 proposal, the EPA derived three potential MCLGs for perchlorate of 18, 56, and 90 µg/L for the most sensitive life-_stage ~~utilizing~~using the best available peer reviewed science in accordance with the SDWA. ~~The proposed~~After considering public comment, the EPA used these potential MCLGs ~~are~~as the levels of public health concern ~~used~~in assessing the frequency of occurrence of perchlorate in this regulatory determination. These MCLGs were set at levels to avoid IQ decrements of 1, 2, and 3 points respectively in the most sensitive life stage, the children of hypothyroxinemic women with low iodine intake. The EPA proposed an MCLG of 56 µg/L~~.~~ and alternative MCLG values of 18 and 90 µg/L.

The rationale used in deriving the numerical values is presented in greater detail in the EPA's technical support document titled "Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (USEPA, 2019b).

The EPA compared these potential MCLG values to the updated perchlorate UCMR 1 occurrence data set. A comprehensive description of the perchlorate occurrence data is presented in Section VI of the 2019 proposal. It is also available in the "Perchlorate Occurrence and Monitoring Report" (USEPA, 2019a).

The occurrence data for perchlorate ~~was~~were collected from 3,865 PWSs between 2001 and 2005 under the UCMR 1. ~~The Agency has~~In the 2019 proposal, the EPA modified ~~its~~the UCMR 1 data set in response to concerns raised by stakeholders regarding the data quality and to represent current conditions in California and Massachusetts, which have enacted perchlorate regulations since the UCMR 1 data ~~was~~were collected. Massachusetts promulgated a drinking water standard for perchlorate of 2 µg/L in 2006 [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"8DPpSrv3","properties":{"formattedCitation":"(MassDEP, 2006)","plainCitation":"(MassDEP, 2006)","noteIndex":0},"citationItems":[{"id":151,"uris":["http://zotero.org/groups/945096/items/9893MBZH"],"uri":["http://zotero.org/groups/945096/items/9893MBZH"],"itemData":{"id":151,"type":"personal_communication","title":"Letter to Public Water Suppliers concerning new perchlorate regulations","URL":"https://www.mass.gov/lists/perchlorate-background-information-and-standards#perchlorate---final-standards-","author":[{"literal":"MassDEP"}],"issued":{"date-parts":[["2006"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], and California promulgated a drinking water standard of 6 µg/L in 2007 [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"cfr6HNhg","properties":{"formattedCitation":"(California Department of Public Health, 2007)","plainCitation":"(California Department of Public Health, 2007)","noteIndex":0},"citationItems":[{"id":150,"uris":["http://zotero.org/groups/945096/items/RA45NKLQ"],"uri":["http://zotero.org/groups/945096/items/RA45NKLQ"],"itemData":{"id":150,"type":"personal_communication","title":"State Adoption of a Perchlorate Standard","URL":"https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/docum ents/perchlorate/AdoptionMemotoWaterSystems-10-2007.pdf","author":[{"literal":"California Department of Public Health"}],"issued":{"date-parts":[["2007"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Systems in these states are now required to keep perchlorate levels in drinking water below their state limits. As discussed below, the EPA finds that perchlorate levels in drinking water and sources of drinking water have decreased since the ~~UCMR1~~UCMR 1 data collection. The main factors contributing to the decrease in perchlorate levels are the promulgation of drinking water regulations for perchlorate in California and Massachusetts and the ongoing remediation efforts in the state of Nevada to address perchlorate contamination in groundwater adjacent to the lower Colorado River upstream of Lake Mead.

To update the occurrence data for systems sampled during UCMR 1 from California and Massachusetts, the EPA identified all systems and corresponding entry points which had reported perchlorate detections in UCMR 1. Once the systems and entry points with detections were appropriately identified, the EPA then used a combination of available data from Consumer Confidence Reports (CCRs) and perchlorate compliance monitoring data from California (https://sdwis.waterboards.ca.gov/PDWW/) and Massachusetts (https://www.mass.gov/service-details/public-water-supplier-document-search) to match current compliance monitoring data (where available) to the corresponding water systems and entry points sampled during UCMR 1.

~~With these updates,~~ The EPA has determined that the UCMR 1 data with these updates are the best available data collected in accordance with accepted methods regarding the frequency and level of perchlorate nationally. The UCMR 1 data are from a census of the large water systems (serving more than 10,000 people) and a statistically representative sample of small water systems that provides the best available, national assessment of perchlorate occurrence in drinking water.

The EPA used entry point maximum measurements to estimate potential baseline occurrence and exposure at levels that exceed the potential MCLG thresholds. The maximum measurements indicate highest perchlorate levels reported in at least one quarterly sample from surface water systems and at least one semi-annual sample from ground water systems.

Table 1: Perchlorate Occurrence and Exposure (Updated UCMR 1 Data Set)

Threshold Concentration (µg/L)	Entry Points with Detections above Threshold	Water Systems with Detections above Threshold	Percent of U.S. Water Systems with Detections above Threshold	Population Served
18 µg/L	17	15	0.03 %	620,560
56 µg/L	2	2	0.004 %	32,432
90 µg/L	1	1	0.002 %	25,972

Table 1 presents the number and percentage of water systems that reported perchlorate at levels exceeding the three proposed MCLG threshold concentrations. In summary, the updated perchlorate occurrence information suggests that at an MCLG of 18 µg/L, there would be 15 systems (0.03% of all water systems in the U.S.) that would exceed the threshold, at an MCLG of 56 µg/L, two systems (0.004% of all water systems in the U.S.) would exceed the threshold, and finally one system would exceed the MCLG threshold of 90 µg/L. Based on the analysis of drinking water occurrence presented in the 2019 proposal and the data summarized in Table 1 and the range of potential MCLGs, the EPA concludes that perchlorate does not occur ~~at~~with a frequency and at levels of public health concern in public water systems.

While the EPA has made its conclusion that perchlorate ~~occurs infrequently~~does not occur at a frequency and at levels of public health concern in public water systems based on the updated UCMR 1 data, the EPA also sought to find additional information about the perchlorate levels at the 15 water systems that had at least one reported result greater than 18 µg/L in the updated UCMR 1 data. The EPA found that perchlorate levels have been reduced at many of these water systems. Although these water systems were not required to take actions to reduce perchlorate in drinking water, many had conducted additional monitoring for perchlorate and found decreased levels or had taken mitigation efforts to address perchlorate, confirming the EPA's conclusion described above. The status of each of these systems is described in Table 2 below.

Table 2: Update on Systems with Perchlorate levels above 18 µg/L in the UCMR 1

State	System Name	Range of UCMR 1 Results (µg/L)**	Update on Mitigation and Levels of Perchlorate++
Florida	Sebring Water	ND-70	The EPA contacted the Sebring system in January 2020. Operations personnel indicated that no follow-up/updated monitoring data for perchlorate are available.

State	System Name	Range of UCMR 1 Results (µg/L)**	Update on Mitigation and Levels of Perchlorate++
Florida	Manatee County Utilities Dept	ND-30	Researchers contacted the system to identify the source of perchlorate. System personnel attributed the sole perchlorate detection under ~~UCMR1~~UCMR 1 to analytical error. System personnel indicated that three other quarterly samples collected under ~~UCMR1~~UCMR 1 as well as other subsequent perchlorate sampling efforts were non-detect. Source: AWWA (2008)
Georgia	Oconee Co.-Watkinsville	38 (single sample)	Researchers contacted the system and found that a perchlorate contaminated well was removed from service in 2003. The system indicates that perchlorate is no longer detected. Source: Luis et al. (2019)
Louisiana	St. Charles Water District 1 East Bank	ND-24	The EPA was not able to identify updated data on perchlorate levels for this system.
Maryland	City of Aberdeen	ND-19	The system's 2018 Consumer Confidence Report (CCR) indicates that perchlorate was not detected. According to the Maryland Department of Environment, perchlorate was not detected in this system in 2019. In addition, researchers contacted the system and found that there has been no detection of perchlorate since treatment was installed in 2009. Source: Luis et al. (2019)
Maryland	Chapel Hill - Aberdeen Proving Grounds	ND-20	The EPA contacted the Chapel Hill System in January 2020. Water system personnel indicate that the Chapel Hill WTP was taken off-line and was replaced with a new treatment plant and five new production wells. The new treatment plant started operations on January 27, 2020. System personnel also indicate that monitoring was conducted in November 2019 and perchlorate was not detected in either the source well water or the finished water. In

State	System Name	Range of UCMR 1 Results (μg/L)**	Update on Mitigation and Levels of Perchlorate++
			addition, according to the Maryland Department of Environment, perchlorate was not detected in this system in 2019.
Mississippi	Hilldale Water District	ND-20	The EPA contacted the Hilldale System in January 2020. Water system personnel indicated that no follow-up/updated monitoring data for perchlorate are available.
New Mexico	Deming Municipal Water System	15-20	Data from the EPA's SDWIS/FED database indicates that the entry point that reported detections in ~~UCMR1~~UCMR 1 (Well #3) is now inactive (i.e., the contaminated source is no longer in use). ~~Source: SDWIS/FED (2016).~~
Nevada	City of Henderson	6-23	Researchers report that the perchlorate levels described in the system's CCR ranged from non-detect to 9.7 μg/L. Source AWWA (2008).
Ohio	Fairfield City PWS	6-27	The EPA contacted the Fairfield City System in January 2020. Water system personnel indicated that follow-up monitoring was conducted after ~~UCMR1~~UCMR 1, between 2002 and 2004. The Ohio EPA provided copies of the follow-up monitoring results which indicate that results at the entry point ranged from non-detect to 13 μg/L.
Ohio	Hecla Water Association-Plant PWS	ND-32	The EPA contacted the Hecla Water Association System in January 2020. Water system personnel indicated that that no follow-up/updated monitoring data for perchlorate are available.
Oklahoma	Enid	ND-30	The EPA reviewed Oklahoma's monitoring data and did not find any monitoring results reported for perchlorate.
Pennsylvania	Meadville Area Water Authority	ND-33	The EPA contacted the Meadville System in January 2020. Water system personnel indicated that no

State	System Name	Range of UCMR 1 Results (µg/L)**	Update on Mitigation and Levels of Perchlorate++
			follow-up/updated monitoring data for perchlorate are available.
Puerto Rico	Utuado Urbano	ND-420	The EPA contacted the Puerto Rico Aqueduct and Sewer Authority (PRASA) in January 2019. PRASA personnel indicated that no updated monitoring data for perchlorate are available. *NOTE: The PRASA personnel stated that the Utuado water system was significantly impacted by hurricane Maria and monitoring records from years prior to 2017 were lost.*
Texas	City of Levelland	ND-32	Researchers found that a water storage tank was the source of perchlorate contamination, the wells feeding the tank were tested by the state and perchlorate was not detected. The water tank was shut off from service. Source: Luis et al. (2019).

** - Values have been rounded. ND describes a sampling event where perchlorate was not detected at or above the UCMR 1 minimum reporting level of 4 µg/L. UCMR 1 results collected between 2001 and 2005.

++ - To obtain updated data and/or information regarding perchlorate levels, the EPA reviewed Consumer Confidence Reports and other publicly available data, as well as published studies. In addition, the EPA contacted some water systems for information about current perchlorate levels. (USEPA, 2020b)

C. Is there a meaningful opportunity for the reduction of health risks from perchlorate for persons served by public water systems?

The ~~Agency's~~EPA's analysis presented in the 2019 proposal demonstrates that a NPDWR for perchlorate does not present a meaningful opportunity for health risk reduction for persons served by public water systems. As discussed above, the EPA found that perchlorate occurs with very low frequency at levels of public health concern. Based on updated UCMR 1 occurrence information, there were 15 water systems (0.03% of all water systems in the U.S.) that detected perchlorate in drinking water above the lowest proposed alternative MCLG of 18 μg/L and only 1 system had a detection above the proposed alternative MCLG of 90 μg/L. Specifically, Table 1 presents the population served by PWSs that were monitored under UCMR 1 for which the highest reported perchlorate concentration was greater than the identified thresholds. The EPA estimates[2] that the number of people who may be potentially consuming water containing perchlorate at levels that could exceed the levels of concern for perchlorate could range between 26,000 ~~to~~and 620,000. The small number of water systems with perchlorate levels greater than identified thresholds and the corresponding small population served provides ample support for the EPA's conclusion that the regulation of perchlorate does not present a "meaningful opportunity for health risk reduction for persons served by public water systems," within the meaning of the SDWA, section 1412(b)(1)(A)(iii).

The EPA also considered the findings of the Health Risk Reduction and Cost Analysis (HRRCA, USEPA 2019c) as additional information supporting withdrawal of the regulatory determination. The HRRCA for perchlorate (which was presented in the 2019 proposal) provides a unique set of economic data indicators that are not available for regulatory determinations because the HRRCA is required for a proposed NPDWR under SDWA Section 1412(b)(3)(C),

[2] The values shown in Table 1 are based on the revised UCMR 1 data. The EPA also applied statistical sampling weights to the small systems results to extrapolate to national results. There was one small system included in the statistical sample stratum which had a perchlorate measurement exceeding 18 μg/L. Accordingly, the EPA estimates that approximately 41,000 small system customers may be exposed to perchlorate greater than 18 μg/L.

but is not ~~prepared~~required to support a regulatory determination. ~~Perchlorate is a unique contaminant for which~~Accordingly, because the ~~Agency has done significant new analysis not undertaken for~~EPA initially determined that perchlorate met the criteria for regulation and began the regulatory ~~determinations. Accordingly,~~analysis process, the HRRCA was available with respect to perchlorate, and the Agency considered this comprehensive economic analysis in informing its decision to withdraw the regulatory determination.

Specifically, the HRRCA provides a description of the potential ~~quantifiable and non-quantifiable~~ benefits and costs of a drinking water regulation for perchlorate. For all potential regulatory levels considered for perchlorate (18, 56, and 90 μg/L) the total costs associated with establishing a regulation were substantially higher than the potential range of ~~quantifiable~~ benefits. The infrequent occurrence of perchlorate at levels of health concern imposes high monitoring and administrative cost burdens on public water systems and the states, while having little impact on health risk reductions and the associated low estimates of benefits.

Based on a comparison of costs and benefits estimated at the three potential regulatory levels, the EPA determined in the 2019 proposal that the benefits of establishing a drinking water regulation for perchlorate do not justify the potential costs.

A drinking water regulation for perchlorate would impose significant burden on states and water systems, mainly associated with requirements for monitoring but which would result in very few systems having to take action to reduce perchlorate levels. It is of paramount importance that water systems (particularly medium, small and economically distressed systems)

focus their limited resources on actions that ensure compliance with existing ~~NPDWR~~NPDWRs and ~~sustain~~maintain their technical, managerial, and financial capacity ~~maintain~~ to improve system operations and -the quality of water being provided to their customers rather than spending resources monitoring for contaminants that are unlikely to occur.

D. What is the EPA's final regulatory determination on perchlorate?

Based on the EPA's ~~new~~ analysis of the best available public health information, and after careful review and consideration of public comments on the June 2019 proposal, the Agency is withdrawing its 2011 determination and is ~~now~~ making a final determination to not ~~to~~ regulate perchlorate. Accordingly, the EPA will not issue a NPDWR for perchlorate at this time. While the EPA has found that perchlorate may have an adverse effect on human health, based on the analysis presented in this notice and supporting record, the EPA has determined that perchlorate does not occur in public water systems ~~at~~with a frequency and at levels of public health concern and that regulation of perchlorate does not present a meaningful opportunity to reduce health risks for persons served by public water systems. This conclusion is based on the best available peer reviewed science and data collected in accordance with accepted methods on perchlorate health effects and occurrence.

Commented [BC2]: Why was this added? I recommend not having it there – but am interesting in knowing if OGC advised this change.

IV. Summary of Key Public Comments on Perchlorate

The EPA received approximately 1,500 comments from individuals or organizations on the June 2019 proposal. This section briefly discusses the key technical issues raised by commenters and the EPA's response. Comments are also addressed in the ''Comment Response

Document for the Final Regulatory Action for Perchlorate'' (USEPA, 2020a) available at http://www.regulations.gov (Docket ID No. EPA–HQ–OW–2018–0780).

A. SDWA Statutory Requirements and the EPA's Authority

The EPA received comments stating the Agency should promulgate an MCLG and MCL for perchlorate and comments stating the Agency should not promulgate a regulation. After considering these comments the ~~Agency~~EPA has re-evaluated perchlorate in accordance with the SDWA, section 1412~~.~~(b~~.~~)(1)(A)~~)~~, which requires that the ~~EPA~~Agency promulgate a NPDWR if (i) the contaminant may have an adverse effect on the health of persons; (ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and (iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

The ~~Agency~~EPA has determined, based upon the best available peer reviewed science and data collected in accordance with accepted methods, that perchlorate does not occur ~~with~~at a frequency and at levels of public health concern, and ~~there is not~~that regulation of perchlorate does not present a meaningful opportunity for health risk reduction. ~~Therefore,~~Because perchlorate does not meet the ~~Agency has determined not~~ statutory criteria for regulation, the EPA lacks the authority to ~~promulgate~~issue a MCLG or NPDWR for perchlorate~~.~~, and is therefore withdrawing its 2011 regulatory determination and issuing this final determination to not regulate perchlorate. For more information regarding EPA's statutory authority to withdraw its regulatory determination, see Section II.C above.

B. Health Effects Assessment

Health Effects/MCLG Derivation

The ~~Agency~~EPA received comments indicating that the ~~EPA~~Agency should utilize different approaches to derive the MCLG for perchlorate including approaches that some states used to develop their perchlorate advisory levels or drinking water standards. The ~~Agency~~EPA considered a number of alternative approaches to develop the MCLG for perchlorate and in accordance with the SDWA, section 1412(e~~)~~), the Agency sought recommendations from the Science Advisory Board. The EPA derived the proposed MCLG for perchlorate based on the approach recommended by the Science Advisory Board (SAB) (SAB for the U.S. EPA, 2013). The SAB recommended that *"the EPA derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling based upon its mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters."* The EPA has implemented these recommendations and has obtained two independent peer reviews of the analysis. These peer reviewers stated that: "*Overall, the panel agreed that the EPA and its collaborators have prepared a highly innovative state-of-the-science set of quantitative tools to evaluate neurodevelopmental effects that could arise from drinking water exposure to perchlorate. While there is always room for improvement of the models,* *with limited additional work to address the committee's comments below, the current models are fit-for-purpose to determine an MCLG*" (External Peer Reviewers ~~forUSEPA~~for USEPA, 2018, p. 2).

The EPA received comments indicating the most sensitive life stages were not selected and/or considered in the Agency's approach. The EPA disagrees. Gestational exposure to perchlorate during neurodevelopment is the most sensitive time period. The NRC concluded that the population most sensitive ~~population~~ to perchlorate exposure are "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a1mn5hjprkt","properties":{"formattedCitation":"(National Research Council (NRC), 2005b)","plainCitation":"(National Research Council (NRC), 2005b)","noteIndex":0},"citationItems":[{"id":350,"uris":["http://zotero.org/groups/945096/items/TN6HMC9D"],"uri":["http://zotero.org/groups/945096/items/TN6HMC9D"],"itemData":{"id":350,"type":"book","title":"Health Implications of Perchlorate Ingestion","publisher":"National Academies Press","publisher-place":"Washington, DC","event-place":"Washington, DC","author":[{"literal":"National Research Council (NRC)"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. In addition, there is clear evidence that disrupted maternal thyroid hormone levels during gestation can impact neurodevelopment later in life (Alexander et al., 2017; Costeira et al., 2011; Endendijk et al., 2017; Ghassabian, Bongers-Schokking, Henrichs, Jaddoe, & Visser, 2011; Glinoer & Delange, 2000; Glinoer & Rovet, 2009; Gyllenberg et al., 2016; Henrichs et al., 2010; Korevaar et al., 2016; Morreale de Escobar, Obregón, & Escobar del Rey, 2004; Noten et al., 2015; Pop et al., 2003, 1999; SAB for the U.S. EPA, 2013; Thompson et al., 2018; van Mil et al., 2012; Wang et al., 2016; Zoeller & Rovet, 2004; Zoeller et al., 2007). ~~The EPA's analysis concludes that~~ The available data demonstrate that the fetus of the first trimester pregnant mother, when compared to other life-stages, experiences the greatest impact from ~~equivalent doses~~the same dose of perchlorate ~~exposure~~, which is described in detail in Section 6 of the document "Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (USEPA, 2019a). ~~In addition, the EPA disagrees~~Some commenters suggested that the bottle-fed ~~infants are the most~~infant is a more sensitive ~~population~~ life-stage. The EPA disagrees as described in the January 2017 Peer Review Report on the original Biologically Based Dose Response (BBDR) model, the bottle-fed infant's thyroid hormone levels were not impacted by doses of perchlorate up to 20 µg/day (External Peer Reviewers for USEPA, 2017). This lack of any impact is due primarily to the iodine in the formula, which offsets the impact of perchlorate on the thyroid.

The ~~Agency~~EPA received comments advocating for the use of ~~a~~the population-based approach~~.~~ evaluating the shift in the proportion of a population that would fall below a hypothyroxinemic cut point under a perchlorate exposure scenario. The ~~Agency~~EPA chose to develop the MCLG using dose-response functions from the epidemiological literature to estimate neurodevelopmental impacts in the offspring of pregnant women exposed to perchlorate. The EPA selected this proposed approach because it is consistent with the SDWA's definition of a MCLG to avoid adverse health effects and because it is most consistent with the SAB recommendations. In addition, the fact that thyroid hormone levels vary by reference population and that there is not a defined value representing hypothyroxinemia makes the population-based approach less desirable than the approach selected (USEPA, ~~2018b~~2018).

End Point Selection/Basis

The ~~Agency~~EPA received comments regarding the magnitude of an IQ change which should be used in ~~considering~~deriving the MCLG. ~~Many comments stated that the Agency should at most consider a 1% IQ change. However, several commenters stated a 3% change is too small to have a meaningful impact and suggested the Agency consider a higher IQ percent change.~~ The ~~Agency's~~EPA's proposed MCLG was based upon avoiding a 2% change in IQ in the most sensitive life stage and the EPA also requested comment on alternative options for the MCLG that would respectively avoid 1% or 3% change in IQ in the most sensitive ~~lifestage~~life stage. Many comments stated that the EPA should at most consider a 1% IQ change. However, several commenters stated a 3% change is too small to have a meaningful impact and suggested the EPA consider a higher IQ percent change.

The EPA uses a variety of science policy approaches to select points of departure for developing regulatory values. For instance, in noncancer risk assessment the EPA often uses a percentage change in value. When assessing toxicological data, a 10 ~~percent~~% extra risk (for discrete data), or a 1 standard deviation (i.e., 15 IQ points) change from the mean (for continuous data) is often used (USEPA, 2012). A smaller response to inform a POD has been applied when using epidemiological literature because there is an inherently more direct relationship between the study results and the exposure context and health endpoint.

Commented [BC3]: Can you send me the source for this and the page number? Thanks.

Given the difficulty in identifying a response below which no adverse impact occurs when considering a continuous outcome in the human population, the EPA looked to its Benchmark Dose Guidance (2012) for insight regarding a starting point. Specifically, ''[a] BMR of 1% has typically been used for quantal human data from epidemiology studies'' (p. 21, USEPA, 2012). For the specific context of setting an MCLG for perchlorate, the EPA ~~made a policy decision to evaluate~~evaluated the level of perchlorate in water associated with a 1 ~~percent~~% decrease, a 2 ~~percent~~% decrease, and a 3 percent decrease in the mean population IQ (i.e., 1, 2 and 3 IQ points).

In evaluating the frequency and level of occurrence of perchlorate in drinking water the ~~Agency~~EPA has found that perchlorate does not occur with frequency even at the lowest alternative MCLG of 18 µg/L which is based upon avoiding a 1% change in IQ in the most sensitive ~~lifestage~~life stage.

The ~~Agency~~EPA received comments that the proposed MCLG did not incorporate an adequate margin of safety to comply with the SDWA. The ~~Agency~~EPA disagrees that ~~there was a failure~~it failed to use an adequate margin of safety. The ~~Agency's~~EPA's assessment focused upon the most sensitive subset of the population, specifically offspring whose mothers had low (75 µg/day) iodine intake and were ~~hypothyroximemic~~hypothyroxinemic (fT4 in the lowest 10th percentile of the population). In addition, to account for uncertainties and to ensure the most sensitive subset of the population is protected ~~within~~with an adequate margin of safety, a 3-fold uncertainty factor was applied to the proposed MCLG calculation (USEPA, 2019a). More discussion on the uncertainty factor is presented in the section "Consideration of Uncertainties."

The EPA received some comments stating that the selection of the study for informing the relationship between maternal hormone levels (fT4) and IQ was inadequately described. Other comments ~~support~~supported the ~~Agency's~~EPA's study selection. The EPA concludes that selection of the Korevaar et al. (2016) study is appropriate because that study provides the most robust data available with a clear measure of neurodevelopment that can be expressed as a function of changing maternal fT4 exposure, which is necessary to the development of the model.

BBDR and PBPK Models

The ~~Agency~~EPA received comments indicating the BBDR model was not transparent, scientifically valid, or based on robust data. The ~~Agency~~EPA disagrees. The model represents the best available peer reviewed science and ~~utilizes~~uses the best available data to inform a MCLG for perchlorate. The EPA does not believe there is a significant lack of transparency with respect to the assumptions related to the BBDR model. Appendix A of the EPA's Proposed MCLG Approaches report outlines the justification for all assumptions used in the development of the BBDR model (USEPA, 2019a). The EPA also disagrees with the assertion the BBDR model is far too uncertain to be relied upon as the basis for the derivation of the RfD. The EPA has used the best available science to calibrate the pharmacokinetic aspects of the BBDR model. The development of the BBDR model was ~~performed~~ in response to SAB recommendations and a model was deemed to be a more ~~superior~~refined approach to estimating a dose-response relationship between perchlorate exposure and maternal fT4 than anything that was available in the current scientific literature. The EPA disputes the claim that there are issues with the scientific validity of the BBDR model as the Agency conducted a peer review of the approach proposed and the reviewers stated the approach was "fit for purpose" to inform a MCLG for perchlorate (External Peer Reviewers for U.S. EPA, 2018, p. 2).

Consideration of Uncertainties

The ~~Agency~~EPA received comments on the ~~EPA's~~Agency's use of Uncertainty Factors (UFs~~),~~); with most commenters ~~suggested~~suggesting that the EPA should consider a higher UF. The ~~Agency~~EPA thoroughly considered the application of UFs when deriving the RfDs and followed guidance presented in "A review of the reference dose and reference concentration processes" (USEPA, 2002). The ~~Agency believes~~EPA concluded that the UFs are adequately justified and subsequently no changes have been made. Justification for each of the UFs ~~described in this comment~~ can be found in Section 11 of the Agency's MCLG Derivation report (USEPA, 2019a).

The ~~Agency~~EPA selected a UF of 3 for inter-individual variability because the Agency specifically modeled groups within the population that are identified as likely to be at greater risk ~~to~~of the adverse effects from perchlorate in drinking water (i.e., the fetus of the iodide deficient pregnant mother). The ~~Agency~~EPA selected model parameters to account for the most sensitive individuals in that group (i.e., muted TSH feedback, low fT4 values, low-iodine intake). As discussed in the MCLG Derivation report, the EPA has attempted to select the most appropriate inputs to protect the most sensitive population with an adequate margin of safety (USEPA, 2019a). The ~~Agency~~EPA has determined that the selection of a UF of 3 for inter-individual variability is justified. As described in the MCLG Derivation report, because the output from the BBDR model is specific to the sensitive population ~~and therefore the Agency has made no change in~~the EPA concluded that the UF of 3 is appropriate. In regards to variation in sensitivity among the members of the human population (i.e., inter-individual variability), section 4.4.5.3 of the EPA guidance "A review of the reference dose and reference concentration process" (USEPA, 2002) document states, "In general, the Technical Panel reaffirms the importance of this UF, recommending that reduction of the intraspecies UF from a default of 10 be considered only if data are sufficiently representative of the exposure/dose-response data for the most susceptible subpopulation(s). Similar to the interspecies UF, the intraspecies UF can be considered to consist of both a toxicokinetic and toxicodynamic portion (i.e. 10^0.5 each)" (USEPA, 2002). Given that the BBDR model significantly accounts for differences within the human population, the full UF of 10 is not warranted.

One commenter suggested using a UF greater than 1 to account for ~~LOAEL-to-NOAEL~~ the extrapolation~~,~~ of the lowest-observed adverse effect level (LOAEL) to the no-observed-adverse-effect-level (NOAEL). LOAELs and NOAELs were not identified or used by the EPA in its assessment because the Agency ~~has determined that the IQ~~ employed a sophisticated BBDR modeling approach, which was coupled with extrapolation to changes ~~presented as options in the 2019 proposal~~in IQ using linear regression, to determine a POD that would not be expected to represent ~~NOAELs.~~an adverse effect. Therefore, ~~including~~ a UF ~~to account for extrapolating from a LOAEL to a NOAEL~~of 1 is ~~not needed. Additional~~appropriate. Other commenters suggested incorporating UFs for database deficiencies. Based on the findings of the NRC report, the EPA has previously concluded that this UF was not needed for deficiencies in the perchlorate database (NRC, 2005; USEPA, 2005a). The EPA believes that a UF of 1 to account for database deficiencies is still appropriate given that the state of the perchlorate database has only increased since 2005.

C. *Occurrence Analysis*

The EPA received comments suggesting that the revised UCMR 1 data did not provide an adequate estimate ~~about~~of the perchlorate occurrence in drinking water systems. Some commenters indicated that the age of the collected data rendered the occurrence analysis obsolete and overestimated, since it no longer captures current lower contamination conditions ~~which~~that have been achieved due to mitigation measures taken in the Colorado River Basin. Other commenters criticized the EPA for replacing UCMR 1 data with compliance data for the States of California and Massachusetts.

The EPA recognizes that changes in perchlorate levels (increasing or decreasing) may have occurred in water systems since the UCMR 1 samples were collected between 2001 to 2005. The ~~Agency~~EPA updated the UCMR 1 data set to improve its accuracy in representing the current conditions for states that have enacted perchlorate regulations since the UCMR 1 monitoring was conducted. As outlined in the June 26, 2019 proposal, the EPA updated occurrence data for California and Massachusetts with current compliance data as reported by the states. Systems from these two states that were sampled during the UCMR 1 and that had reported perchlorate detections were updated with more recently measured values taken from current compliance monitoring data from Consumer Confidence Reports and state-level perchlorate compliance monitoring data to match corresponding water systems and entry points ~~between the two sources~~.

The EPA has determined that the updated UCMR 1 data are the best available data collected in accordance with accepted methods on the frequency and level of perchlorate occurrence in drinking water on a national scale.

V. Conclusion

With this withdrawal of the 2011 perchlorate regulatory determination and final determination to not ~~to~~ regulate perchlorate, the EPA announces that there will be no NPDWR for perchlorate at this time. The EPA could consider re-listing perchlorate on the CCL and could proceed to regulation in the future if the occurrence or health risk information changes. As with other unregulated contaminants, the EPA ~~could address the~~will consider addressing limited instances of elevated levels of perchlorate by working with the affected system and state, as appropriate.

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List of Subjects in 40 CFR Parts 141 and 142

Administrative practice and procedure, Chemicals, Indians-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated:____________________

____

Andrew ~~R.~~ Wheeler,

Administrator.

DELIBERATIVE DRAFT
TO BE UPDATED FOLLOWING INTER AGENCY REVIEW

MEMORANDUM

SUBJECT: Notice of Final Action on Perchlorate
(Tier 1 Action; SAN 5555; RIN 2040-AF28) – **ACTION MEMORANDUM**

FROM: David P. Ross
Assistant Administrator (4101M)

THRU: Office of Policy (1803A)
Office of Executive Secretariat (1105A)

TO: Andrew J. Wheeler
Administrator (1101A)

PURPOSE

Attached for your signature is the action titled "Notice of Final Action on Perchlorate."

On February 11, 2011, the EPA published a determination to regulate perchlorate in drinking water (76 FR 7762). On June 26, 2019 (84 FR 30524), the EPA published the proposed National Primary Drinking Water Regulation (NPDWR) for Perchlorate and requested public comments on multiple alternative actions, including withdrawing the Agency's 2011 determination to regulate perchlorate. The EPA received approximately 1,500 comments on the proposed rule.

In this notice, the EPA is withdrawing the 2011 Regulatory Determination and is making a final determination not to regulate perchlorate based on the Agency's consideration of public comments and the best available information.

DEADLINE/TIMELINE

Section 1412(b)(1)(A) of the Safe Drinking Water Act (SDWA) requires the EPA to issue a proposed NPDWR within 24 months of the final regulatory determination and a final NPDWR within 18 months after the proposal. However, when the EPA consulted with the Science Advisory Board (SAB) regarding a planned methodology for deriving the maximum contaminant level goal (MCLG) for perchlorate, the Agency received recommendations to develop a physiologically based pharmacokinetic model (i.e., a biologically based dose-response model (BBDR)) to predict the effects of perchlorate exposure on thyroid function in pregnant women and their children, instead. The EPA collaborated with Food and Drug Administration scientists to perform the modeling recommended by the SAB and completed the analysis and associated peer reviews in March 2018. This delayed the EPA in proposing a NPDWR within 24 months.

In February 2016, the Natural Resources Defense Council (NRDC) filed a lawsuit for failure of the EPA to perform its mandatory duties of proposing and finalizing a regulation for perchlorate in accordance with timelines provided in the SDWA. On October 18, 2016, the U.S. District Court for the Southern District of New York entered a Consent Decree, requiring the EPA to sign for publication a proposal for a MCLG and NPDWR for perchlorate in drinking water no later than October 31, 2018, and to sign for publication a final MCLG and NPDWR for perchlorate in drinking water no later than December 19, 2019. The Court later extended the deadline for the EPA to propose a MCLG and NPDWR for perchlorate in drinking water to May 28, 2019, and extended the date for signature of a final MCLG and NPDWR no later than June 19, 2020.

In compliance with the deadline established in the Consent Decree, on May 23, 2019, the Administrator signed a proposed rulemaking notice seeking public comment on a range of options regarding the regulation of perchlorate in public drinking water systems. The EPA published the proposed rule in the *Federal Register* on June 26, 2019. The public comment period for the proposal ended on August 26, 2019, and the EPA received approximately 1,500 comments.

DESCRIPTION of the ATION

Perchlorate is an inorganic anion that occurs naturally. It is also manufactured as an oxidizer for rockets, missiles, and fireworks and can be an impurity in hypochlorite disinfectants. The public may be exposed to perchlorate through food and drinking water. At certain levels, perchlorate can prevent the thyroid gland from getting enough iodine, which can affect thyroid hormone production. For pregnant women with low iodine levels, sufficient changes in thyroid hormone levels may cause changes in the child's brain development. For infants, changes to thyroid hormone function can also impact brain development.

The SDWA sets forth three criteria that must be met for the EPA to issue a MCLG and promulgate a NPDWR. Specifically, the EPA must determine that (1) "the contaminant may have an adverse effect on the health of persons;" (2) "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern;" and (3) "in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems" (SDWA 1412(b)(1)(A)).

In the attached notice, the EPA concludes that, based on new data and the Agency's analysis since the issuance of the 2011 Regulatory Determination, perchlorate does not in fact meet the statutorily prescribed criteria for regulation. The new data and analysis indicate that perchlorate does not occur in public water systems with a frequency and at levels of public health concern. Specifically, the new peer-reviewed health effects analysis resulted in the health based proposed MCLG and proposed alternative MCLGs for perchlorate that are higher concentrations in drinking water (18 – 90 µg/L) than the concentrations that the EPA considered to be levels of public health concern in the Agency's analysis for the determination to regulate in 2011 (1-47 µg/L). In addition, the updated occurrence analysis shows that the frequency of occurrence of perchlorate in public water systems at levels exceeding any of the alternative proposed MCLGs (0.38% - 0.02%) is significantly lower than the frequency considered in the EPA's analysis for the 2011 Regulatory Determination (4% - 0.39%). Based on this information, the

DELIBERATIVE DRAFT
TO BE UPDATED FOLLOWING INTER AGENCY REVIEW

EPA is announcing the Agency's conclusion that perchlorate does not occur in public water systems "with a frequency…of public health concern" and, therefore, regulation of perchlorate does not present a "meaningful opportunity for health risk reduction for persons served by public water systems" as required for regulation under the SDWA. Accordingly, perchlorate no longer meets the statutory criteria for regulation because the EPA does not have the authority to issue a MCLG or promulgate a NPDWR for perchlorate.

Therefore, the EPA is not issuing a final MCLG or NPDWR for perchlorate. However, the EPA maintains the authority to re-list perchlorate on future Contaminant Candidate Lists and proceed with regulating perchlorate in the future if occurrence or risk information changes. The EPA will consider addressing limited instances of elevated levels of perchlorate by working with the affected system and state, as appropriate.

Commented [BC1]: Is this statement in the final action? Why are we including it here?

STAKEHOLDER INVOLVEMENT and ANTICIPATED RESPONSE

The EPA considered the approximately 1,500 comments that were submitted on the proposed regulation. The EPA also consulted with the National Drinking Water Advisory regarding the proposed regulation. The EPA expects a variety of reactions and responses from stakeholders. The NRDC will likely sue the EPA for failure to comply with the Consent Decree and will likely challenge the Agency's authority to withdraw a Regulatory Determination. Officials from the States of California and Massachusetts, public health groups and environmental groups will likely state that a low perchlorate maximum contaminant level is needed to protect children's health. Industry groups, including the American Water Works Association, the Perchlorate Study Group, the American Chemistry Council, and the U.S. Chamber of Commerce will support the decision not to regulate perchlorate in drinking water. These groups will agree with the EPA's determinations that perchlorate does not occur frequently at levels of public health concern and there is not a meaningful opportunity for health risk reduction for persons served by public water systems.

INTERNAL DEVELOPMENT and REVIEW PROCESS

The attached notice reflects the direction provided by the Administrator in the Options Selection meetings held on January 9 and March 18, 2020. The Office of Water (OW) convened a Final Agency Review meeting for this action on May 7, 2020. The following offices concurred without comment: the Office of Research and Development, the Office of Land and Emergency Management, the Office of Air and Radiation, and the Office of Chemical Safety and Pollution Prevention. The following offices concurred with comment: the Office of General Counsel (OGC), the Office of Policy (OP), and the Office of Children's Health Protection (OCHP). The OW has incorporated revisions identified in the comments from the OGC. The OW has also incorporated most of the suggested revisions identified by the OP, the key exception being that we are not incorporating OP's recommendation to not list the cost benefit analysis as a factor in the decision to withdraw the regulatory determination. The OW has worked with OGC to incorporate language that clarifies that this does not set a precedent for future regulatory determinations. The OW is not incorporating the majority of recommendations made by the OCHP, which address the health effects and occurrence analysis and are issues we have evaluated previously, including in response to OCHP's input on the proposal and in response to public comments.

DELIBERATIVE DRAFT
TO BE UPDATED FOLLOWING INTER AGENCY REVIEW

INTERAGENCY REVIEW
The Office of Management and Budget initiated review of the *Federal Register* notice: "Notice of Final Action on Perchlorate" on [date placeholder].

PEER REVIEW
For the proposed rulemaking, the OW followed the EPA's Peer Review Handbook and Agency policy titled "Conflicts of Interest Review Process for Contractor-Managed Peer Reviews of EPA HISA and ISI Documents" when conducting the peer review of models used to derive the proposed MCLGs for perchlorate. The EPA convened an independent peer review panel to evaluate the BBDR models in 2017 and a second, expert peer review panel in 2018 to evaluate the update of the BBDR model and approaches to link the BBDR model output to neurodevelopment endpoints in epidemiology studies to derive an MCLG. The EPA also sought input from the SAB, as required by the SDWA, prior to developing the proposed MCLGs.

RECOMMENDATION
I recommend that you sign the attached *Federal Register* notice titled "Notice of Final Action on Perchlorate."

Attachments (2)

Message

From: Bertrand, Charlotte [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F044D768E05842E1B75321FF6010E1B8-BERTRAND, CHARLOTTE]
Sent: 1/8/2020 3:09:03 PM
To: Mclain, Jennifer [Mclain.Jennifer@epa.gov]
CC: Aguirre, Janita [Aguirre.Janita@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Nagle, Deborah [Nagle.Deborah@epa.gov]; Behl, Betsy [Behl.Betsy@epa.gov]; Wendelowski, Karyn [wendelowski.karyn@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]
Subject: RE: revised perchlorate briefing
Attachments: Option Selection for Perchlorate 1-9-20v2.cb.docx

Thanks! I made a few tweaks in areas that I highlighted in green. Let me know if you are ok with those suggested changes. Looks good.
Cc'ing Lee for his input too.

From: Mclain, Jennifer <Mclain.Jennifer@epa.gov>
Sent: Tuesday, January 07, 2020 5:51 PM
To: Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Aguirre, Janita <Aguirre.Janita@epa.gov>; Mejias, Melissa <mejias.melissa@epa.gov>; Tiago, Joseph <Tiago.Joseph@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Nagle, Deborah <Nagle.Deborah@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Wendelowski, Karyn <wendelowski.karyn@epa.gov>
Subject: revised perchlorate briefing

Charlotte
Attached is a revised perchlorate briefing document per our meeting with Dave this morning. I've also attached the track changes version so you can see the specifics of where we made changes.
Please let us know if you have any questions.
Jennifer

Jennifer L. McLain, Director
Office of Ground Water and Drinking Water
U.S. EPA

6560-50-P

ENVI RONMENTAL PROTECTION AGENCY

40 CFR Parts 141, and 142

[EPA-HQ-OW-2018-0780; FRL-XXXX-XX-OW]

RIN 2040-AF28

National Primary Drinking Water Regulations: Proposed Perchlorate Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule, request for public comment.

SUMMARY: The Environmental Protection Agency (EPA) is proposing a drinking water regulation for perchlorate and a health-based Maximum Contaminant Level Goal (MCLG) in accordance with the Safe Drinking Water Act (SDWA). The EPA is proposing to set both the enforceable Maximum Contaminant Level (MCL) for the perchlorate regulation and the perchlorate MCLG at 0.056 mg/L (56 μg/L). The EPA is proposing requirements for water systems to conduct monitoring and reporting for perchlorate and to provide information about perchlorate to their consumers through public notification and consumer confidence reports. This proposal includes requirements for primacy agencies that implement the public water system supervision program under the SDWA. This proposal also includes a list of treatment technologies that would enable water systems to comply with the MCL, including affordable compliance technologies for small systems serving 10,000 persons or less.

In addition to the proposed regulation, the EPA is requesting comment on three alternatives: 1) whether the MCL and MCLG for perchlorate should be set at 0.018 mg/L (18

μg/L), 2) whether the MCL and MCLG for perchlorate should be set at 0.090 mg/L (90 μg/L), or 3) whether instead of issuing a national primary drinking water regulation, the EPA should withdraw the Agency's February 11, 2011, determination to regulate perchlorate in drinking water based on new information that indicates that perchlorate does not occur in public water systems with a frequency and at levels of public health concern and there may not be a meaningful opportunity for health risk reduction through a drinking water regulation. Under this last alternative, the final action would be a withdrawal of the determination to regulate and there would be no MCLG or national primary drinking water regulation for perchlorate.

DATES: Comments must be received on or before *[insert date 60 days after publication in the* Federal Register*]*. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before *[insert date 30 days after date of publication in the* Federal Register*]*.

ADDRESSES: Submit your comments, identified by Docket ID No. **EPA-HQ-OW-2018-0780**, at [HYPERLINK "http://www.regulations.gov"]. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit [HYPERLINK "http://www2.epa.gov/dockets/commenting-epa-dockets"].

FOR FURTHER INFORMATION CONTACT: Samuel Hernandez, Office of Ground Water and Drinking Water, Standards and Risk Management Division (Mail Code 4607M), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone number: (202) 564-1735; email address: hernandez.samuel@epa.gov.

SUPPLEMENTARY INFORMATION: This proposed rule is organized as follows:

I. General Information

A. What is the EPA Proposing?

This action contains a proposal and three alternatives for public comment. First, the EPA proposes to establish a Maximum Contaminant Level Goal (MCLG) and National Primary Drinking Water Regulation (NPDWR) for perchlorate in public water supplies. The EPA proposes an MCLG of 56 μg/L, and to regulate perchlorate in drinking water at an enforceable maximum contaminant level (MCL) of 56 μg/L.

The EPA is proposing an NPDWR for perchlorate in accordance with its February 11, 2011, (76 FR 7762) determination to regulate perchlorate under the SDWA. Based on the best available peer reviewed science at that time, the EPA found that perchlorate met the SDWA's three criteria for regulating a contaminant: 1) the contaminant may have an adverse effect on the health of persons, 2) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems (PWSs) with a frequency and at levels of public health concern, and 3) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

Second, as explained in more detail below, the EPA is soliciting comment on two alternative MCLG/MCL values of 18 µg/L and 90 µg/L respectively. Third, in light of new considerations that have come to the EPA's attention since it issued its positive regulatory determination in 2011, including information on lower levels of occurrence of perchlorate than the EPA had previously believed to exist and new analysis of the concentration that represents a level of health concern, this action also discusses and requests comment on an alternative action under which the EPA would withdraw its 2011 determination to regulate perchlorate. Under this alternative, there would be no MCLG or NPDWR for perchlorate.

B. Does This Action Apply to Me?

Entities that could potentially be affected include the following:

Category	Examples of potentially affected entities
Public water systems	Community water systems Non-transient, non-community water systems

State and tribal agencies	Agencies responsible for drinking water regulatory development and enforcement

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that could be affected by this action. To determine whether your facility or activities could be affected by this action, you should carefully examine this proposed rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the FOR FURTHER INFORMATION CONTACT section.

II. Background

A. What is Perchlorate?

Perchlorate is a negatively charged inorganic ion that is comprised of one chlorine atom bound to four oxygen atoms (ClO_4-), which is highly stable and mobile in the aqueous environment. Perchlorate comes from both natural and manmade sources. It is formed naturally via atmospheric processes and can be found within mineral deposits in certain geographical areas. It is also produced in the United States, and the most common compounds include ammonium perchlorate and potassium perchlorate used primarily as oxidizers in solid fuels to power rockets, missiles, and fireworks. For the general population, most perchlorate exposure is through the ingestion of contaminated food or drinking water.

B. Statutory Authority

Section 1412(b)(1)(A) of the SDWA requires the EPA to establish NPDWRs for contaminants that may have an adverse effect on the health of persons; that are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and where in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

C. Statutory Framework and Regulatory History

Section 1412(b)(1)(B)(i) of the SDWA requires the EPA to publish every five years a Contaminant Candidate List (CCL). The CCL is a list of drinking water contaminants that are known or anticipated to occur in public water systems and are not currently subject to the EPA drinking water regulations. The EPA uses the CCL to identify priority contaminants for regulatory decision-making and information collection. Contaminants listed on the CCL may require future regulation under the SDWA. The EPA included perchlorate on the first, second, and third CCLs published in 1998, 2005, and 2009.

Once listed on the CCL, the Agency continues to collect data on CCL contaminants to better understand their potential health effects and to determine the levels at which they occur in drinking water. Section 1412(b)(1)(B)(ii) requires that, every five years, the EPA, after public comment, issue a determination whether or not to regulate at least five contaminants on the CCL. For any contaminant that the EPA determines meets the criteria for regulation, under Section 1412(b)(1)(E), the EPA must issue a proposed national primary drinking water regulation within two years and issue a final regulation 18 months after the proposal (which may be extended by 9 months).

As part of its responsibilities under the SDWA, the EPA implements section 1445(a)(2), "Monitoring Program for Unregulated Contaminants." This section requires that once every five years, the EPA issue a list of no more than 30 unregulated contaminants to be monitored by public water system. This monitoring is implemented through the Unregulated Contaminant Monitoring Rule (UCMR), which collects data from community water systems (CWS) and non-transient, non-community water systems (NTNCWS). The UCMR collects data from a census of large water systems (serving more than 10,000 people) and from a statistically representative sample of small water systems. On September 17, 1999, the EPA published its first UCMR (64 FR 50556) which required all large systems and a representative sample of small systems to monitor for perchlorate and 25 other contaminants (USEPA, 1999, 2000b).

The EPA and other federal agencies asked the National Research Council (NRC) to evaluate the health implications of perchlorate ingestion. The NRC concluded that perchlorate exposure inhibits the transport of iodide[1] into the thyroid by a protein molecule knows as the sodium/iodide symporter (NIS), which may lead to decreases in two hormones, thyroxine (T3) and triiodothyronine (T4) and increases in thyroid-stimulating hormone (TSH) [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a1mn5hjprkt","properties":{"formattedCitation":"(National Research Council (NRC), 2005b)","plainCitation":"(National Research Council (NRC), 2005b)","noteIndex":0},"citationItems":[{"id":350,"uris":["http://zotero.org/groups/945096/items/TN6HMC9D"],"uri":["http://zotero.org/groups/945096/items/TN6HMC9D"],"itemData":{"id":

[1] For the purposes of this FRN, "iodine" will be used to refer to dietary intake before entering the body. Once in the body, "iodide" will be used to refer to the ionic form.

350,"type":"book","title":"Health Implications of Perchlorate Ingestion","publisher":"National Academies Press","publisher-place":"Washington, DC","event-place":"Washington, DC","author":[{"literal":"National Research Council (NRC)"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Additionally, the NRC concluded that the most sensitive population to perchlorate exposure are "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" (p. 178). The EPA established a reference dose (RfD) consistent with the recommended National Research Council RfD of 0.7 μg/kg/day for perchlorate. The reference dose is an estimate of a daily exposure to humans that is likely to be without an appreciable risk of adverse effects. This RfD was based on a study [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a3u94lt6me","properties":{"formattedCitation":"(Greer, Goodman, Pleus, & Greer, 2002)","plainCitation":"(Greer, Goodman, Pleus, & Greer, 2002)","noteIndex":0},"citationItems":[{"id":387,"uris":["http://zotero.org/groups/945096/items/6AKUNIX6"],"uri":["http://zotero.org/groups/945096/items/6AKUNIX6"],"itemData":{"id":387,"type":"article-journal","title":"Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans","container-title":"Environmental Health Perspectives","page":"927","volume":"110","issue":"9","author":[{"family":"Greer","given":"Monte A."},{"family":"Goodman","given":"Gay"},{"family":"Pleus","given":"Richard C."},{"family":"Greer","given":"Susan E."}],"issued":{"date-parts":[["2002"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] of perchlorate's inhibition of radioactive iodine uptake in healthy adults and the application of an uncertainty factor of 10 for intraspecies variability [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"0oHz805e","properties":{"formattedCitation":"(USEPA, 2005b)","plainCitation":"(USEPA, 2005b)","noteIndex":0},"citationItems":[{"id":980,"uris":["http://zotero.org/groups/945096/items/LHANJBR6"],"uri":["http://zotero.org/groups/945096/items/LHANJBR6"],"itemData":{"id":980,"type":"article","title":"Integrated Risk Information System (IRIS) Chemical Assessment Summary: Perchlorate (ClO4-) and Perchlorate Salts","publisher":"USEPA National Center for Environmental Assessment","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

In October 2008, the EPA published a preliminary regulatory determination not to regulate perchlorate in drinking water and requested public comment (73 FR 60262). In that preliminary determination, the EPA tentatively concluded that perchlorate did not occur with a frequency and at levels of public health concern and that development of a regulation did not present a meaningful opportunity for health risk reduction for persons served by public water systems. The EPA derived and used a Health Reference Level (HRL) of 15 μg/L based on the RfD of 0.7 μg/kg/day in making this conclusion [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"FZ6WMtAv","properties":{"formattedCitation":"(USEPA,

2008a)","plainCitation":"(USEPA,
2008a)","noteIndex":0},"citationItems":[{"id":934,"uris":["http://zotero.org/groups/945096/items/HBX88QM9"],"uri":["http://zotero.org/groups/945096/items/HBX88QM9"],"itemData":{"id":934,"type":"article-journal","title":"Drinking water: Preliminary regulatory determination on perchlorate","container-title":"Federal Register","volume":"73","issue":"198","abstract":"SUMMARY: This action presents EPA's preliminary regulatory determination for perchlorate in accordance with the Safe Drinking Water Act (SDWA). The Agency has determined that a national primary drinking water regulation (NPDWR) for perchlorate would not present \"a meaningful opportunity for health risk reduction for persons served by public water systems." The SDWA requires EPA to make determinations every five years of whether to regulate at least five contaminants on the Contaminant Candidate List (CCL). EPA included perchlorate on the first and second CCLs that were published in the Federal Register on March 2, 1998 and February 24, 2005. Most recently, EPA presented final regulatory determinations regarding 11 contaminants on the second CCL in a notice published in the Federal Register on July 30, 2008. In today's action, EPA presents supporting rationale and requests public comment on its preliminary regulatory determination for perchlorate. EPA will make a final regulatory determination for perchlorate after considering comments and information provided in the 30-day comment period following this notice. EPA plans to publish a health advisory for perchlorate at the time the Agency publishes its final regulatory determination to provide State and local public health officials with technical information that they may use in addressing local contamination.","ISSN":"ISSN 0097-6326 EISSN 2167-

2520","shortTitle":"Federal Register","journalAbbreviation":"Fed. Reg.","language":"English","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2008"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Based primarily on the UCMR 1 occurrence data, the EPA estimated that less than 1% of drinking water systems (serving approximately 1 million people) had perchlorate levels above the HRL of 15 µg/L. Based on this information the Agency determined that perchlorate did not occur frequently at levels of health concern. The EPA also determined that there was not a meaningful opportunity for a NPDWR to reduce health risks.

In January 2009 the EPA published an interim health advisory for perchlorate of 15 µg/L, consistent with the HRL derivation for perchlorate of 15 µg/L described above. Health Advisories are non-enforceable and non-regulatory and provide technical information to state agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. Health Advisories provide the public, including the most sensitive populations, with a margin of protection from a lifetime of exposure. For perchlorate, the health advisory was developed for subchronic exposure (USEPA 2008d).

In August 2009, the EPA published a supplemental request for comment with a new analysis that derived potential alternative HRLs for 14 life stages, including infants and children. The analysis used the RfD of 0.7 µg/kg/day and life stage-specific bodyweight and exposure information (74 FR 41883; USEPA, 2009a). After careful consideration of public comments on the October 2008 and August 2009 notices, on February 11, 2011, the EPA published its determination to regulate perchlorate (76 FR 7762; USEPA, 2011a). The Agency stated then that when considering the alternative HRL benchmarks described in the 2009 notice, the likelihood of perchlorate to occur at levels of concern had significantly increased in comparison to the levels described on the 2008 preliminary negative determination. The EPA concluded that as many as 16 million people could potentially be exposed to perchlorate at levels of concern, up from 1 million people originally described in the 2008 notice.

In its 2011 determination, the Agency found that perchlorate may have an adverse effect on the health of persons, that it is known to occur in public drinking water systems with a frequency and at levels that present a public health concern, and in the judgment of the Administrator, regulation of perchlorate presented a meaningful opportunity for health risk reduction for persons served by public water systems. As a result of the determination, and as required by Section 1412(b)(1)(E), the EPA initiated the process to develop an MCLG and NPDWR for perchlorate as described in this notice.

In September 2012, the U.S. Chamber of Commerce (the Chamber) submitted to the EPA a Request for Correction under the Information Quality Act regarding the EPA's regulatory determination. In the request, the Chamber claimed that the UCMR 1 data did not comply with data quality guidelines and were not representative of current conditions. In response to this request, the EPA reassessed the data and removed certain source water samples that could be paired with appropriate follow-up samples located at the entry point to the distribution system. The EPA also updated the UCMR 1 data for systems in California and Massachusetts using state compliance data to reflect current occurrence conditions after state regulatory limits for perchlorate were implemented.

In response to a lawsuit brought to enforce the deadlines in Section 1412(b)(1)(E), the U.S. District Court for the Southern District of New York entered a consent decree, requiring the EPA to propose an NPDWR with a proposed MCLG for perchlorate in drinking water no later than October 31, 2018, and finalize an NPDWR and MCLG for perchlorate in drinking water no later than December 19, 2019. The deadline for the EPA to propose an NPDWR with a proposed MCLG for perchlorate in drinking water was later extended to May 28, 2019. The consent decree is available in the docket for today's proposed rule.

III. Assessment and Modeling of the Health Effects of Perchlorate

Perchlorate inhibits uptake of iodide into the thyroid gland by competitively binding to the protein that transports iodide with the NIS from blood to the thyroid gland (ATSDR, 2008; Greer et al., 2002; NRC, 2005; SAB 2013; Taylor et al., 2013). Iodide is necessary for the synthesis of thyroid hormones and decreased iodide uptake into the thyroid can adversely affect thyroid hormone production (SAB for the U.S. EPA, 2013; Blount et al., 2006; Steinmaus et al., 2007, 2013, 2016, McMullen et al., 2017; Knight et al., 2018). These changes in thyroid hormone levels in a pregnant woman may be linked to changes in the neurodevelopment of her offspring (SAB for the U.S. EPA, 2013; Korevaar et al., 2016; Fan and Wu, 2016; Wang et al., 2016; Alexander et al., 2017; Thompson et al., 2018). In addition, alterations in thyroid homeostasis may impact other body systems including the reproductive (Alexander et al., 2017;

Hou et al., 2016; Maraka et al., 2016) and cardiovascular systems (Asvold et al., 2012; Sun et al., 2017).

More specifically, exposure to perchlorate is known to inhibit the uptake of iodide by the thyroid gland through the NIS (NRC, 2005; SAB for the U.S. EPA, 2013). A sufficient inhibition of iodide uptake results in iodide deficiency within the thyroid. Given that T3 and T4 require iodide for production, a decrease in intra-thyroidal iodide can result in decreased production of these hormones. This could in turn result in increased TSH, the hormone that acts on the thyroid gland to stimulate iodide uptake to increase thyroid hormone production [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"eF6zWm7L","properties":{"formattedCitation":"(ATSDR, 2008; Blount, Pirkle, Osterloh, Valentin-Blasini, & Caldwell, 2006; National Research Council (NRC), 2005; Steinmaus, Miller, Cushing, Blount, & Smith, 2013; Steinmaus et al., 2016)","plainCitation":"(ATSDR, 2008; Blount, Pirkle, Osterloh, Valentin-Blasini, & Caldwell, 2006; National Research Council (NRC), 2005; Steinmaus, Miller, Cushing, Blount, & Smith, 2013; Steinmaus et al., 2016)","noteIndex":0},"citationItems":[{"id":428,"uris":["http://zotero.org/groups/945096/items/UIANA947"],"uri":["http://zotero.org/groups/945096/items/UIANA947"],"itemData":{"id":428,"type":"bill","title":"Toxicological Profile for Perchlorates","author":[{"family":"ATSDR","given":""}],"issued":{"date-parts":[["2008"]]}}},{"id":203,"uris":["http://zotero.org/groups/945096/items/UW4TFPNI"],"uri":["http://zotero.org/groups/945096/items/UW4TFPNI"],"itemData":{"id":203,"type":"article-journal","title":"Urinary perchlorate and thyroid tormone levels in adolescent and adult men and women living in the United States","container-title":"Environmental Health Perspectives","page":"1865-1871","volume":"114","issue":"12","source":"CrossRef","DOI":"10.1289/ehp.9466","ISSN":"0091-6765","language":"en","author":[{"family":"Blount","given":"Benjamin C."},{"family":"Pirkle","given":"James L."},{"family":"Osterloh","given":"John D."},{"family":"Valentin-Blasini","given":"Liza"},{"family":"Caldwell","given":"Kathleen L."}],"issued":{"date-parts":[["2006"]]}}},{"id":349,"uris":["http://zotero.org/groups/945096/items/TN6HMC9D"],"uri":["http://zotero.org/groups/945096/items/TN6HMC9D"],"itemData":{"id":349,"type":"book","title":"Health Implications of Perchlorate Ingestion","publisher":"National Academies Press","publisher-place":"Washington, DC","event-place":"Washington, DC","author":[{"literal":"National Research Council (NRC)"}],"issued":{"date-parts":[["2005"]]}}},{"id":39,"uris":["http://zotero.org/groups/945096/items/35VPNIKR"],"uri":["http://zotero.org/groups/945096/items/35VPNIKR"],"itemData":{"id":39,"type":"article-journal","title":"Combined effects of perchlorate, thiocyanate, and iodine on thyroid function in the national health and nutrition examination survey 2007-8","container-title":"Environmental research","volume":"123","source":"www.ncbi.nlm.nih.gov","abstract":"Perchlorate, thiocyanate, and low iodine intake can all decrease iodide intake into the thyroid gland. This can reduce thyroid hormone production since iodide is a key component of thyroid hormone. Previous research has suggested that each of these factors

...","URL":"https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3857960/","DOI":"10.1016/j.envres.2013.01.005","note":"PMID: 23473920","language":"en","author":[{"family":"Steinmaus","given":"Craig"},{"family":"Miller","given":"Mark D."},{"family":"Cushing","given":"Lara"},{"family":"Blount","given":"Benjamin C."},{"family":"Smith","given":"Allan H."}],"issued":{"date-parts":[["2013",5]]},"accessed":{"date-parts":[["2017",5,5]]}}},{"id":211,"uris":["http://zotero.org/groups/945096/items/H4FH49VS"],"uri":["http://zotero.org/groups/945096/items/H4FH49VS"],"itemData":{"id":211,"type":"article-journal","title":"Thyroid hormones and moderate exposure toperchlorate during pregnancy in women in southern California","container-title":"Environmental Health Perspectives","page":"861-867","volume":"124","issue":"6","source":"PubMed","abstract":"BACKGROUND: Findings from national surveys suggest that everyone in the United States is exposed to perchlorate. At high doses, perchlorate, thiocyanate, and nitrate inhibit iodide uptake into the thyroid and decrease thyroid hormone production. Small changes in thyroid hormones during pregnancy, including changes within normal reference ranges, have been linked to cognitive function declines in the offspring.\nOBJECTIVES: We evaluated the potential effects of low environmental exposures to perchlorate on thyroid function.\nMETHODS: Serum thyroid hormones and anti-thyroid antibodies and urinary perchlorate, thiocyanate, nitrate, and iodide concentrations were measured in 1,880 pregnant women from San Diego County, California, during 2000-2003, a period when much of the area's water supply was contaminated from an industrial plant with perchlorate at levels near the 2007 California regulatory standard of 6 μg/L. Linear regression was used to evaluate associations between urinary perchlorate and serum thyroid hormone concentrations in models adjusted for urinary creatinine and thiocyanate, maternal age and education, ethnicity, and gestational age at serum collection.\nRESULTS: The median urinary perchlorate concentration was 6.5 μg/L, about two times higher than in the general U.S.\nPOPULATION: Adjusted associations were identified between increasing log10 perchlorate and decreasing total thyroxine (T4) [regression coefficient (β) = -0.70; 95% CI: -1.06, -0.34], decreasing free thyroxine (fT4) (β = -0.053; 95% CI: -0.092, -0.013), and increasing log10 thyroid-stimulating hormone (β = 0.071; 95% CI: 0.008, 0.133).\nCONCLUSIONS: These results suggest that environmental perchlorate exposures may affect thyroid hormone production during pregnancy. This could have implications for public health given widespread perchlorate exposure and the importance of thyroid hormone in fetal neurodevelopment.\nCITATION: Steinmaus C, Pearl M, Kharrazi M, Blount BC, Miller MD, Pearce EN, Valentin-Blasini L, DeLorenze G, Hoofnagle AN, Liaw J. 2016. Thyroid hormones and moderate exposure to perchlorate during pregnancy in women in Southern California. Environ Health Perspect 124:861-867;

http://dx.doi.org/10.1289/ehp.1409614.","DOI":"10.1289/ehp.1409614","ISSN":"1552-9924","note":"PMID: 26485730\nPMCID: PMC4892913","journalAbbreviation":"Environ. Health

Perspect.","language":"eng","author":[{"family":"Steinmaus","given":"Craig"},{"family":"Pearl

","given":"Michelle"},{"family":"Kharrazi","given":"Martin"},{"family":"Blount","given":"Benjamin C."},{"family":"Miller","given":"Mark D."},{"family":"Pearce","given":"Elizabeth N."},{"family":"Valentin-Blasini","given":"Liza"},{"family":"DeLorenze","given":"Gerald"},{"family":"Hoofnagle","given":"Andrew N."},{"family":"Liaw","given":"Jane"}],"issued":{"date-parts":[["2016",6]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. For populations with developing brains (e.g., fetuses, neonates, and children), disruptions in homeostatic thyroid hormone function can result in adverse neurodevelopmental effects (Alexander et al., 2017; Glinoer & Delange, 2000; Glinoer & Rovet, 2009; SAB for the U.S. EPA, 2013). Specifically, decreased maternal thyroid hormone levels during pregnancy, including in the hypothyroxinemic range[2], have been linked to decrements in neurocognitive function in offspring (Alexander et al., 2017; Thompson et al., 2018; Wang et al., 2016). There is also limited evidence to suggest an association with other adverse neurodevelopmental outcomes including ADHD, expressive language delay, reduced school performance, autism, and delayed cognitive development (Alexander et al., 2017; Ghassabian, Bongers-Schokking, Henrichs, Jaddoe, & Visser, 2011; Gyllenberg et al., 2016; Henrichs et al., 2010; Korevaar et al., 2016, Noten et al., 2015; Pop et al., 2003, 1999; SAB for the U.S. EPA, 2013; van Mil et al., 2012).

[2] Maternal hypothyroxinemia is defined as TSH in the reference range and fT4 in the lower percentiles. The SAB notes that hypothyroxinemia has been defined by a "variety of cutoffs…ranging from fT4 below the 10th or 5th percentiles to below the 2.5th percentile" (SAB, 2013, p.10) in the population.

The difficulty in estimating the likelihood and magnitude of the potential implications of perchlorate's mode of action on expressed neurodevelopmental health effects in humans exposed to perchlorate during development is the lack of robust epidemiological studies, especially in sensitive populations. Therefore, based on the known mode of action of perchlorate the Agency estimated potential health risks using a novel approach suggested by the EPA's Science Advisory Board (SAB for the U.S. EPA, 2013). The EPA's approach to estimating perchlorate risks has evolved over time with improved research and modeling capabilities. The following sections describe information sources the EPA used in its assessment as well as the regulatory process followed by the Agency in its decision making.

A. 2008 Preliminary Regulatory Determination

In 2005, at the request of the EPA and other federal agencies, the NRC evaluated the health implications of perchlorate ingestion. The NRC concluded that perchlorate exposure could inhibit the transport of iodide into the thyroid, leading to thyroid hormone deficiency (NRC, 2005). A significant inhibition of iodide uptake results in intra-thyroid iodide deficiency, decreased synthesis of T3 and T4, and increased TSH. The NRC also concluded that a prolonged decrease of thyroid hormones is potentially more likely to have adverse effects in sensitive populations (e.g., the fetuses of pregnant women who might have hypothyroidism or iodide deficiency). Based on these findings, the NRC recommended a reference dose of 0.7 μg/kg/day.

Based on NRC's analysis, the EPA established a perchlorate reference dose (RfD) of 0.7 μg/kg/day in 2005 (USEPA, 2005). This value was based on a no observed effect level (NOEL) of 7 μg/kg/day identified from a study (Greer, Goodman, Pleus, & Greer, 2002) of perchlorate's inhibition of radioactive iodine uptake in healthy adults and the application of an uncertainty factor of 10 for intraspecies variability.

As discussed above, in 2008, the EPA derived an HRL of 15 μg/L using the RfD of 0.7 μg/kg/day, a default bodyweight of 70 kg, a default drinking water consumption rate of 2 L/day, and a perchlorate-specific relative source contribution (RSC) of 62 percent that was derived for a pregnant woman (USEPA, 2008a) (73 FR 60262). The RSC is the percentage of the RfD remaining for drinking water after other sources of exposure to perchlorate (i.e., food) have been considered. The EPA's HRL was calculated to offer a margin of protection against adverse health effects to the subpopulation identified by the NAS as likely the most sensitive to the effects of perchlorate exposure, fetuses.

B. 2009 Supplemental Request for Comment and 2011 Final Regulatory Determination

The EPA received over 33,000 comments in response to its 2008 preliminary determination to not regulate perchlorate (USEPA, 2011a). After reviewing the comments, the EPA developed alternative HRLs for other sensitive populations in addition to fetuses of pregnant women. The EPA developed alternative HRLs for 14 life stages including infants and children. The EPA also evaluated the occurrence of perchlorate at levels above these alternative HRLs using the UCMR 1 occurrence data.

The analysis used the RfD of 0.7 μg/kg/day and life stage-specific bodyweight and exposure information (i.e., drinking water intake, RSC) for each of the 14 life stages evaluated. The resulting HRLs ranged from 1 μg/L to 47 μg/L. In August 2009, the EPA published a supplemental request for comment with the new analysis and HRLs (74 FR 41883; USEPA, 2009a). After careful consideration of public comments, on February 11, 2011, the EPA published its final determination to regulate perchlorate (76 FR 7762; USEPA, 2011a).

C. Science Advisory Board Recommendations

As required by Section 1412(d) of the SDWA, as part of the NPDWR development process, the EPA requested comments from the Science Advisory Board (SAB) in 2012, seeking guidance on how best to consider and interpret the life stage information, the epidemiologic and biomonitoring data since the NRC report, physiologically-based pharmacokinetic (PBPK) analyses, and the totality of perchlorate health information to derive an MCLG for perchlorate. The SAB recommended the following:

- derive a perchlorate MCLG that addresses sensitive life stages through physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling based upon perchlorate's mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters;
- expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;
- utilize a mode-of-action framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition – to thyroid hormone changes – and finally to neurodevelopmental impacts; and
- "Extend the [BBDR] model expeditiously to…provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to

neurodevelopmental outcomes during sensitive early life stages" (SAB for the U.S. EPA, 2013, p. 19).

This SAB-proposed framework would incorporate the previous endpoint of iodide uptake inhibition that was the basis for the RfD as part of a broader and more comprehensive framework that links perchlorate exposure to adverse neurodevelopmental outcomes. It also focuses on the smaller changes in thyroid hormones (specifically free T4 (fT4)) that are associated with maternal hypothyroxinemia and subsequent adverse neurodevelopmental health effects rather than the significant changes in thyroid hormones (both fT4 and TSH) that are associated with hypothyroidism.

D. Perchlorate Model Development and Peer Reviews

To address the SAB recommendations, the EPA revised an existing PBPK/PD model that describes the dynamics of perchlorate, iodide, and thyroid hormones in a woman during the third trimester of pregnancy (Lumen, Mattie, & Fisher, 2013; USEPA, 2009b). The EPA also created its own Biologically Based Dose Response (BBDR) models that included the additional sensitive life stages identified by the SAB, i.e., breast- and bottle-fed neonates and infants (SAB for the U.S. EPA, 2013, p. 19).

To determine whether the Agency had implemented the SAB recommendations for modeling thyroid hormone changes, the EPA convened an independent peer review panel to evaluate the BBDR models in January 2017 (External Peer Reviewers for USEPA, 2017). In addition to estimating effects on breast fed infants, several reviewers recommended that the EPA shift the primary focus of its analysis to modeling the exposure implications to the fetus during early pregnancy. This was based on the knowledge that fetuses lack a functioning thyroid gland until approximately 16 gestational weeks and the substantial epidemiological evidence linking early pregnancy low fT4 levels with adverse neurodevelopmental outcomes [ADDIN EN.CITE <EndNote><Cite><Author>Morreale de Escobar</Author><Year>2004</Year><RecNum>49</RecNum><DisplayText>(G Morreale de Escobar, Obregón, & Escobar del Rey, 2004)</DisplayText><record><rec-number>49</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1437077734">49</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Morreale de Escobar, G</author><author>Obregón, M J</author><author>Escobar del Rey, F</author></authors></contributors><titles><title>Role of thyroid hormone during early brain development</title><secondary-title>European Journal of Endocrinology</secondary-title></titles><periodical><full-title>European Journal of Endocrinology</full-title></periodical><pages>U25-U37</pages><volume>151</volume><number>Suppl 3</number><dates><year>2004</year><pub-dates><date>November 1, 2004</date></pub-dates></dates><urls><related-urls><url>http://www.eje-online.org/content/151/Suppl_3/U25.abstract</url></related-urls></urls><electronic-resource-num>10.1530/eje.0.151U025</electronic-resource-num></record></Cite></EndNote>]. Specifically, the SAB recommended that the EPA use specific sensitive populations to develop the MCLG for perchlorate: “the fetuses of hypothyroxinemic pregnant women, and infants exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women" (SAB for the U.S. EPA, 2013, p. 19).

The EPA considered all recommendations from the 2017 peer review. The previously developed BBDR model describing perchlorate's effects in the third trimester (Lumen, Mattie, & Fisher, 2013; USEPA, 2009b) was calibrated only for that phase of pregnancy, not for the first trimester, and lacked a description of TSH signaling (feedback) that becomes significant as individuals become hypothyroxinemic or hypothyroid. In particular, this signaling was considered necessary to accurately predict responses of women with very low iodine intake, which was also part of the 2017 peer review recommendations. Therefore, the Lumen et al., (2009b) model needed to be revised to address these recommendations and the EPA implemented those changes needed to increase the scientific rigor of the model and modeling results. These modifications include:

- extending the model to early pregnancy;
- incorporating biological feedback control of hormone production via TSH signaling, such that the model can describe lower levels of iodide nutrition;
- calibrating the model and evaluating its behavior for upper and lower percentiles of the population, as well as the population median; and
- conducting an uncertainty analysis for key parameters.

The EPA convened a second independent peer review panel in January 2018 to evaluate these updates to the BBDR model. The EPA also presented several approaches in the draft *Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for*

Perchlorate in Drinking Water (MCLG Approaches Report) to link the thyroid hormone changes in a pregnant mother predicted by the BBDR model to neurodevelopmental effects using evidence from the epidemiological literature (External Peer Review for U.S. EPA, 2018). The 2018 peer review identified a variety of strengths and limitations of the modeling (to be discussed in more detail later in this notice). The peer review panel was largely supportive of the efforts described in the MCLG Approaches Report, as evidenced by the following from the peer review final report:

> *Overall, the panel agreed that the EPA and its collaborators have prepared a highly innovative state-of-the-science set of quantitative tools to evaluate neurodevelopmental effects that could arise from drinking water exposure to perchlorate. While there is always room for improvement of the models, with limited additional work to address the committee's comments [in the peer-reviewed report], the current models are fit-for-purpose to determine an MCLG (External Peer Reviewers for U.S. EPA, 2018, p. 2).*

The EPA also presented an alternative, population-based approach evaluating the shift in the proportion of the population that would fall below a hypothyroxinemic cut point, given exposure to perchlorate (Section 7 of the MCLG Approaches Report). This approach does not directly connect the BBDR output to a neurodevelopmental endpoint. However, for pregnant women in early pregnancy, this shift could be related to avoiding an increase in the population of offspring's risk of adverse neurodevelopmental impacts. The 2018 peer review identified strengths associated with this approach, including

1) the central premise, that hypothyroxinemia is associated with adverse neurodevelopmental effects is supported by a large number of studies, including categorical studies; 2) this approach encompasses a variety of adverse neurodevelopmental outcomes, as indicated by these studies, rather than focusing on one or a limited number of adverse outcomes, as with the two-stage approach; and 3) this approach avoids all of the uncertainties associated with determining a quantitative relationship between a specific maternal fT4 level and the magnitude an adverse neurodevelopmental effect. (*External Peer Reviewers for U.S. EPA, 2018, p. 7)*

The peer reviewers expressed concern about hypothyroxinemia being a precursor effect, rather than an adverse health outcome, which they argued may create difficulties in explaining the basis for an MCLG based on this approach to some audiences. However, the EPA has used precursor effects as the basis for setting regulatory and non-regulatory limits previously. The peer-review panel also expressed concern that a standard definition of hypothyroxinemia has not yet been established, as clinicians use varying fT4 thresholds to define their own working definition of the condition. This also could lead to difficulties communicating the population at risk for developing this precursor effect as a result of perchlorate exposure.

Ultimately, the EPA chose to develop the MCLG using dose-response functions from the epidemiological literature to estimate neurodevelopmental impacts in the offspring of pregnant women exposed to perchlorate. The EPA selected this proposed approach because it is consistent with the SDWA's definition of an MCLG to avoid adverse health effects and because it is most consistent with the SAB recommendations. The EPA is requesting public comment in Section

XIV on the adequacies and uncertainties of the methodology to derive the MCLG including the decision not to pursue this population-based approach for setting the MCLG.

Based on the comments of the peer reviewers, the EPA's final analysis informing the derivation of the MCLG and benefits of avoided perchlorate exposure is based upon a 2-step approach to modeling the neurodevelopmental effects on offspring of pregnant women exposed to perchlorate in drinking water (see Figure 1). In summary, because of the known mode of action, the lack of epidemiological studies particularly in the sensitive populations and the direction of the SAB to use a "data-driven approach [which] represents a more rigorous way to address differences in biology and exposure between adults and sensitive life stages" (p. 2, SAB 2013 for U.S. EPA), the EPA uses a combination of the BBDR model that simulates perchlorate potential impacts on maternal thyroid hormones during pregnancy and the epidemiology literature that relates incremental changes in maternal thyroid hormones to neurodevelopmental outcomes in children. The following sections describe the approach in greater detail, highlighting each step in which decisions and assumptions were made.

Figure 1. Two-Step Modeling Approach to Link Maternal Perchlorate Exposure to Measurable Adverse Neurodevelopmental Impacts in Offspring

[EMBED Visio.Drawing.15]

Note: Process figure does not imply the strength of scientific evidence.

E. Sensitive Population for Deriving MCLG

SDWA 1412(b)(4)(A) requires MCLGs to be set at a concentration in water "at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." SDWA 1412(b)(3)(C)(V) further requires that the EPA "consider the effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population." The EPA has interpreted these requirements to establish MCLGs that avoid adverse effects within the portions of the population that are at greater risk of adverse effects from exposure to the contaminant. The EPA is proposing an MCLG that is developed to protect the fetuses of a first trimester pregnant mother with low-iodine intake levels (i.e., 75 μg/kg/day), low fT4 levels (i.e., 10th percentile of an fT4 distribution for individuals with 75 μg/day iodine intake), and weak TSH feedback strength (i.e., TSH feedback is reduced to be approximately 60 percent less effective than for the median individual). The choice of this population is consistent with discussion by the NRC (2005), and the SAB (2013). The EPA believes that by protecting this population, the other sensitive populations (i.e., breast- and bottle-fed infants) will also be protected. This conclusion is based on the EPA's analysis of predictions of the impact of perchlorate on fT4 levels from the original EPA BBDR model (which was peer reviewed in January of 2017) and an analysis of the literature on the connection between altered thyroid hormones in these life stages, and neurodevelopmental outcomes.

The EPA's original BBDR model demonstrated that perchlorate had minimal impact on the thyroid hormone levels for 30-, 60-, and 90-day formula-fed infants, even at doses as high as 20 μg/kg/day. Specifically, the model demonstrated that "the range of iodine levels in formula is sufficient to almost entirely offset the effects of perchlorate exposure at 30, 60 and 90 days" [ADDIN EN.CITE <EndNote><Cite><Author>U.S.

EPA</Author><Year>2016</Year><RecNum>246</RecNum><Suffix>`; p. 73</Suffix><DisplayText>(U.S. EPA, 2016; p. 73)</DisplayText><record><rec-number>246</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468339271">246</key></foreign-keys><ref-type name="Generic">13</ref-type><contributors><authors><author>U.S. EPA,</author></authors><secondary-authors><author>Paul Schlosser, Teresa Leavens, and Santhini Ramasamy</author></secondary-authors></contributors><titles><title>Biologically based dose response models for the effect of perchlorate on thyroid hormones in the infant, breast feeding mother, pregnant mother, and fetus: model development, revision, and preliminary dose-response analyses </title><secondary-title>Peer Review Draft</secondary-title></titles><dates><year>2016</year></dates><urls></urls></record></Cite></EndNote>]. As a result of these findings the EPA concluded that any MCLG based on the fetus of the first trimester hypothyroxinemic pregnant mother would also protect the formula-fed infant.

To determine if the same would be true for the breast-fed infant, the EPA compared the predicted percent change in fT4 experienced at given doses of perchlorate for both the breast-fed infant and the first trimester pregnant mother at varying doses of iodine intake[3] (50 to 100 μg/day). Assuming 2 or 4 μg/kg/day of perchlorate, the first trimester hypothyroxinemic pregnant mother has a greater percent change in fT4 compared to the 30 and 60 day breast-fed infant at all maternal iodine intake levels evaluated, except for the 30 day breast-fed infant of a

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[3]Given that the current version of the BBDR model contains a TSH feedback loop and the infant models previously developed did not contain this feedback loop, this comparison is done with the feedback loop turned off.

mother consuming only 50 μg/day iodine. However, given that the original BBDR model did not have a TSH feedback loop, T4, fT4, T3 and fT3 predictions for lactating mothers with less than 75 μg/day iodine intake were considered highly uncertain because the thyroid hormone levels had fallen into the hypothyroid range.

The Agency found that there are reports in the scientific literature suggesting that minor perturbations in thyroid hormone levels in the first trimester mother may adversely impact her offspring's neurodevelopment. Specifically, some studies show that children exposed gestationally to maternal hypothyroxinemia (without hypothyroidism) have a higher risk of reduced levels of global and specific cognitive abilities, as well as increased rates of behavior problems including greater dysregulation in early infancy and attentional disorders in childhood [ADDIN EN.CITE ADDIN EN.CITE.DATA]. Notably these effects are correlated with both degree [ADDIN EN.CITE ADDIN EN.CITE.DATA] and duration [ADDIN EN.CITE
<EndNote><Cite><Author>Pop</Author><Year>2003</Year><RecNum>25</RecNum><DisplayText>(Pop et al., 2003)</DisplayText><record><rec-number>25</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1432047641">25</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Pop, V J</author><author>Brouwers, E P</author><author>Vader, H L</author><author>Vulsma, T</author><author>van Baar, A L</author><author>de Vijlder, J J</author></authors></contributors><titles><title>Maternal hypothyroxinemia during early pregnancy and subsequent child development: a 3-year follow-up study</title><secondary-title>Clinical Endocrinology</secondary-

title></titles><periodical><full-title>Clinical Endocrinology</full-title></periodical><pages>282-288</pages><volume>59</volume><section>282</section><dates><year>2003</year></dates><urls></urls></record></Cite></EndNote>] of maternal hypothyroxinemia [ADDIN EN.CITE <EndNote><Cite><Author>SAB</Author><Year>2013</Year><RecNum>50</RecNum><Suffix>`; p. 10</Suffix><DisplayText>(SAB, 2013; p. 10)</DisplayText><record><rec-number>50</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1437138201">50</key></foreign-keys><ref-type name="Government Document">46</ref-type><contributors><authors><author>SAB,</author></authors><secondary-authors><author>U.S. Environmental Protection Agency,</author></secondary-authors></contributors><titles><title>Advice on approaches to derive a maximum contaminant level goal for perchlorate. EPA-SAB-13-004</title></titles><dates><year>2013</year></dates><pub-location>Washington, DC</pub-location><urls></urls></record></Cite></EndNote>].

The EPA did not find analogous evidence linking minor perturbations in thyroid hormones during infancy to adverse neurodevelopmental outcomes in infants. This finding is consistent with conclusions by the California Environmental Protection Agency (CalEPA) in their assessment of a public health goal for perchlorate [ADDIN EN.CITE <EndNote><Cite ExcludeAuth="1"><Author>California Environmental Protection Agency (CalEPA)</Author><Year>2015</Year><RecNum>62</RecNum><Prefix>CalEPA`,

</Prefix><Suffix>`; p. 90</Suffix><DisplayText>(CalEPA, 2015; p. 90)</DisplayText><record><rec-number>62</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1437413166">62</key></foreign-keys><ref-type name="Government Document">46</ref-type><contributors><authors><author>California Environmental Protection Agency (CalEPA),</author></authors><secondary-authors><author>Office of Environmental Health Hazard Assessment</author></secondary-authors></contributors><titles><title>Public health goal for perchlorate in drinking water</title></titles><dates><year>2015</year></dates><urls></urls></record></Cite></EndNote>].

Specifically, two studies evaluated both the impact of maternal hypothyroxinemia and infant fT4 levels on subsequent neurodevelopmental outcomes. [HYPERLINK \l "_ENREF_9" \o "Costeira, 2011 #7"] found that children born to mothers with low fT4 in the first trimester had increased odds of mild-to-severe delays in psychomotor development compared to children born to mothers with normal fT4 levels. However, the authors found that neonatal thyroid status (measured on day 3 after birth) did not influence development. Additionally, [HYPERLINK \l "_ENREF_17" \o "Henrichs, 2010 #928"] found in their evaluation that although maternal hypothyroxinemia was associated with language delay and nonverbal cognitive delay, the neonatal thyroid status (thyroid hormones measured in cord blood) did not explain the relationship between maternal hypothyroxinemia, early pregnancy, and children's cognitive impairment.

The SAB pointed to two lines of evidence supporting their suggestion of the infant as a potentially sensitive population to perchlorate: preterm infants that experience transient hypothyroxinemia of prematurity (THOP) and infants that experience congenital hypothyroidism (SAB for the U.S. EPA, 2013). Thus, sufficient thyroid hormone levels in infancy are necessary for the infant brain to develop properly. However, the best evidence linking perturbations in thyroid hormone levels to disrupted neurodevelopment for infants are in individuals with significant thyroid deficiencies manifesting as clinical conditions (e.g., THOP and congenital hypothyroidism). It is unclear and unknown if minor perturbations in thyroid hormones in infants, such as those that could be caused by environmental levels of perchlorate, would result in adverse neurodevelopmental outcomes similar to those seen in the literature for the offspring of first trimester pregnant mothers with hypothyroxinemia. Given the lack of evidence demonstrating minor perturbations in infant fT4 levels as being associated with neurodevelopmental outcomes, the EPA has concluded that it is appropriate to derive the perchlorate MCLG to protect the first trimester fetus of a pregnant mother with low-iodine intake. The EPA concludes that an MCLG calculated to offer a margin of protection against adverse health effects to these fetuses targets the most sensitive lifestage and will be protective of other potentially sensitive life stages as well.

F. BBDR Model Specification for the Sensitive Population

The BBDR model used to develop the proposed MCLG has two main components:

- a pharmacokinetic model for perchlorate and iodide, which describes chemical absorption, distribution, metabolism, and excretion of perchlorate and iodide; and

- a pharmacodynamic model, which describes the joint effect of varying perchlorate and iodide blood concentrations on thyroidal uptake of iodide and subsequent production of thyroid hormones, including fT4.

The pharmacokinetic model component contains a physiological description of a human mother and fetus during pregnancy (e.g., organ volumes, blood flows) and chemical-specific information (e.g., partition coefficients, volume of distribution, rate constants for transport, metabolism, and elimination) that enable a prediction of perchlorate and iodide internal concentration at the critical target (i.e., thyroidal sodium-iodide symporter of the mother) in association with a particular exposure scenario (route of exposure, age, dose level). This component of the model is similar to many other PBPK models. Because perchlorate does not undergo metabolism in vivo (Clewell et al., 2007), potential uncertainty from this factor of the model is avoided since it does not need to be described.

The pharmacodynamic component of the model uses this internal concentration to simulate how the chemical will act within a known mechanism of action to perturb host systems and lead to a toxic effect.

Thus, the BBDR model estimates serum thyroid hormone levels in the mother at specific gestational weeks, given specific levels of iodine intake, the TSH feedback loop strength, and perchlorate doses. As noted above, to be health protective the EPA chose to model a sensitive individual (an adult woman with low iodine through the first trimester of pregnancy) to derive an MCLG, thereby protecting both this target sensitive population with an adequate margin of safety and those who are less sensitive with an even larger margin of safety.

The BBDR model simulates perchlorate's impact on thyroid hormones at each gestational week from conception to week 16. To derive the MCLG, the EPA selected outputs for gestational week 13 to correspond with the thyroid hormone data reported in Korevaar et al., (2016), which is the basis for the Agency's quantitative relationship between maternal thyroid hormone levels and neurodevelopmental impacts.

Individuals with low iodine intake have increased sensitivity to perchlorate's impact on thyroid hormone levels because the functional iodide reserve of the hypothalamic-pituitary-thyroid (HPT) system is limited [ADDIN EN.CITE <EndNote><Cite><Author>Leung</Author><Year>2010</Year><RecNum>1160</RecNum><DisplayText>(Leung, Pearce, & Braverman, 2010)</DisplayText><record><rec-number>1160</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1495206437">1160</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Leung, A. M.</author><author>Pearce,</author><author>Braverman</author></authors></contributors><titles><title>Perchlorate, iodine and the thyroid</title><secondary-title>Best Practice and Research: Clinical Endocrinology and Metabolism</secondary-title><alt-title>Best Pract Res Clin Endocrinol Metab</alt-title><short-title>Best Practice and Research: Clinical Endocrinology and Metabolism</short-title></titles><alt-periodical><full-title>Best Pract Res Clin Endocrinol Metab</full-title></alt-periodical><pages>133-141</pages><volume>24</volume><number>1</number><dates><year>2010</year></dates>

<isbn>ISSN 1521-690X
EISSN 1532-1908</isbn><label>755955</label><work-type>Review</work-type><urls><related-urls><url>http://dx.doi.org/10.1016/j.beem.2009.08.009</url></related-urls></urls><electronic-resource-num>10.1016/j.beem.2009.08.009</electronic-resource-num><language>English</language></record></Cite></EndNote>]. The EPA selected an iodine intake level of 75 μg/day to simulate an individual with low-iodine intake. This value represents an intake between the 15^{th} and 20^{th} percentile of the women of child bearing age population distribution of estimated iodine intake from the National Health and Nutrition Examination Survey (NHANES). The EPA considered using a lower iodine intake level of 50 μg/day, which represents approximately the 5^{th} percentile of the NHANES distribution. At 50 μg/day of iodine intake, however, the BBDR model predicts TSH levels that would be elevated to within the clinically hypothyroid range before exposure to any perchlorate[4] (TSH

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[4] For the purposes of this analysis, the EPA evaluated the American Thyroid Association's (ATA's) 2017 recommendations for defining hypothyroidism [ADDIN EN.CITE <EndNote><Cite><Author>Alexander</Author><Year>2017</Year><RecNum>1895</RecNum><DisplayText>(Alexander et al., 2017)</DisplayText><record><rec-number>1895</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1497970921">1895</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Alexander, E. K.</author><author>Pearce, E. N.</author><author>Brent, G. A.</author><author>Brown, R. S.</author><author>Chen, H.</author><author>Dosiou, C., </author><author>Sullivan, S.</author></authors></contributors><titles><title>2017 Guidelines of the American Thyroid Association for the diagnosis and management of thyroid disease during pregnancy and the postpartum</title><secondary-title>Thyroid</secondary-title></titles><periodical><full-title>Thyroid</full-title></periodical><pages>315-389</pages><volume>27</volume><number>3</number><dates><year>2017</year></dates><urls></urls></record></Cite></EndNote>]. Specifically the ATA recommends "in the pregnancy setting, maternal hypothyroidism is defined as a TSH concentration elevated beyond the upper limit of the pregnancy-specific reference range" [ADDIN EN.CITE <EndNote><Cite><Author>Alexander</Author><Year>2017</Year><RecNum>1895</RecNum><Pages>332</Pages><DisplayText>(Alexander et al., 2017, p. 332)</DisplayText><record><rec-number>1895</rec-

ranges between 4.51 and 5.41 milli-international units per liter (mIU/L) at zero dose of perchlorate when evaluating gestational weeks 12 or 13). In contrast, at 75 µg/day iodine, the BBDR modeled concentrations of serum fT4 and TSH are significantly reduced from the population median but are still within the euthyroid range. Thus, the intake of 75 µg/day is a better approximation of the sensitive population – the offspring of pregnant women who have low fT4.

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number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1497970921">1895</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Alexander, E. K.</author><author>Pearce, E. N.</author><author>Brent, G. A.</author><author>Brown, R. S.</author><author>Chen, H.</author><author>Dosiou, C., </author><author>Sullivan, S.</author></authors></contributors><titles><title>2017 Guidelines of the American Thyroid Association for the diagnosis and management of thyroid disease during pregnancy and the postpartum</title><secondary-title>Thyroid</secondary-title></titles><periodical><full-title>Thyroid</full-title></periodical><pages>315-389</pages><volume>27</volume><number>3</number><dates><year>2017</year></dates><urls></urls></record></Cite></EndNote>]. ATA goes on to state, in the absence of population- and trimester-specific reference ranges defined by a provider's institute or laboratory, that the TSH reference ranges should be obtained from similar patient populations. From their recommended studies with trimester-specific data on a U.S. population, Lambert-Meserlian et al. [ADDIN EN.CITE <EndNote><Cite ExcludeAuth="1"><Author>Lambert-Messerlian</Author><Year>2008</Year><RecNum>100</RecNum><DisplayText>(2008)</DisplayText><record><rec-number>100</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1443808320">100</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Lambert-Messerlian, Geralyn</author><author>McClain, Monica</author><author>Haddow, James E</author><author>Palomaki, Glenn E</author><author>Canick, Jacob A</author><author>Cleary-Goldman, Jane</author><author>Malone, Fergal D</author><author>Porter, T Flint</author><author>Nyberg, David A</author><author>Bernstein, Peter</author></authors></contributors><titles><title>First-and second-trimester thyroid hormone reference data in pregnant women: a FaSTER (First-and Second-Trimester Evaluation of Risk for aneuploidy) Research Consortium study</title><secondary-title>American journal of obstetrics and gynecology</secondary-title></titles><periodical><full-title>American journal of obstetrics and gynecology</full-title></periodical><pages>62-e1</pages><volume>199</volume><number>1</number><dates><year>2008</year></dates><publisher>Elsevier</publisher><isbn>0002-9378</isbn><urls></urls></record></Cite></EndNote>] is the largest U.S.-based population with a reference range upper bound of 3.37 mIU/L for the first trimester (and 3.35 mIU/L for the second trimester). Therefore, these values were used to compare to BBDR output TSH values in the first trimester (or second trimester in cases of gestational weeks 15 and 16) to determine the presence of hypothyroidism.

TSH increases in response to decreases in T4 have been captured in numerous studies that document the relationship between these hormones[ADDIN EN.CITE ADDIN EN.CITE.DATA]. The EPA designed the BBDR model to depict this feedback regulation by adjusting a set of three parameters: the number of sodium-iodide symporter sites, the T4 synthesis rate, and the T3 synthesis rate. The BBDR model allows for variability in the strength of the TSH feedback by varying these parameters with a variable called "pTSH." For the MCLG analysis, the EPA used a pTSH value of 0.398, which is the ratio of a median value for TSH from NHANES (non-pregnant women) to the 97.5 percentile value from NHANES (non-pregnant women). This value represents an assumption that sensitive individuals with high TSH and average fT4 levels exist, and this is because the stimulus strength of TSH is proportionally weaker. The EPA chose to use a low TSH feedback coefficient to ensure the MCLG is protective of the sensitive population.

Example output from the BBDR model for gestational week 13 and a low TSH feedback coefficient is presented in [REF _Ref517525852 \h * MERGEFORMAT].

Table III-[SEQ Table * ARABIC]. Summary of BBDR Model Results for fT4 Levels: Pregnant Women at Gestational Week 13, Assuming Low (75 µg/day) Iodine Intake and with Muted TSH feedback strength[a][]

Perchlorate Dose (µg/kg/day)	Percentile fT4 (pmol/L)[b] (% decrease from 0 dose)			
	2.5th	5th	10th	50th
0	5.57	6.09	6.70	8.84
1	5.50 (-1.26%)	6.02 (-1.15%)	6.63 (-1.04%)	8.77 (-0.79%)
2	5.43 (-2.45%)	5.96 (-2.24%)	6.56 (-2.04%)	8.71 (-1.54%)
3	5.37 (-3.59%)	5.96 (-3.28%)	6.50 (-2.98%)	8.64 (-2.26%)
4	5.31 (-4.68%)	5.83 (-4.28%)	6.44 (-3.89%)	8.58 (-2.95%)

5	5.25 (-5.73%)	5.77 (-5.23%)	6.38 (-4.76%)	8.52 (-3.60%)
6	5.19 (-6.73%)	5.72 (-6.14%)	6.33 (-5.59%)	8.47 (-4.23%)
7	5.14 (-7.69%)	5.66 (-7.02%)	6.27 (-6.39%)	8.41 (-4.84%)

[a] pTSH = 0.398; see USEPA, (2018b) for additional information on pTSH.
[b] The 50th percentile is direct output from the BBDR model, and additional percentiles are estimated by assuming a normal distribution with a SD of 1.67. All of the examined study data demonstrated a positive skew, and overall the lognormal function demonstrated a better fit than a normal distribution. Despite this, the available study data only accounted for variation due to gestation week and did not account for variation in perchlorate and iodine intake in the measured populations. Because perchlorate and iodine can affect fT4 levels, and this relationship produced the estimated median BBDR values, the distribution around values estimated by the model from perchlorate and iodine intake should account for a small reduction in variation due to the effect of perchlorate and iodine intake. Additionally, as iodine has a demonstrated lognormal distribution with strong right skew (e.g. Blount et al., 2007) and is predicted to have a stronger effect on fT4 than perchlorate (see Section 3). The EPA assumed the error around predicted fT4 would likely be closer to normal than lognormal after accounting for perchlorate and iodine intake.

When modeling changes in fT4, the baseline level of fT4 affects the magnitude of changes seen as a result of perchlorate exposure. Therefore, to predict the impact of perchlorate exposure on the population distribution of fT4 for the identified sensitive population, the EPA estimated a distribution for fT4 plasma concentrations around the median modeled values based on fT4 data from studies that were used to calibrate the BBDR model (C. Li et al., 2014; Männistö et al., 2011; Zhang et al., 2016). The EPA assumed the variation around predicted fT4 concentrations for women with low fT4 of childbearing age would likely be close to normal after accounting for perchlorate and iodine intake, and thus estimated a combined standard deviation (SD) using the distributional information from each of the studies (C. Li et al., 2014; Männistö et al., 2011; Zhang et al., 2016). The EPA then used the estimated combined SD to predict a distribution of fT4 around the median fT4 estimated by the BBDR model. To protect the most sensitive population from adverse effects, the EPA chose to use the 10th percentile from this distribution of baseline fT4 to conduct its analyses to account for variability in thyroid hormones in the population[5].

G. Epidemiological Literature

The SAB recommended that the EPA integrate BBDR model results with data on neurodevelopmental outcomes from epidemiological studies. There is substantial epidemiological evidence that early pregnancy hypothyroxinemia is a risk factor for a variety of adverse neurodevelopmental outcomes, including those related to both cognition and behavior (Costeira et al., 2011; Finken, van Eijsden, Loomans, Vrijkotte, & Rotteveel, 2013; Ghassabian et al., 2014; Gyllenberg et al., 2016; Henrichs et al., 2010; Július et al., 2013; Kooistra, Crawford, van Baar, Brouwers, & Pop, 2006; Korevaar et al., 2016; Y. Li et al., 2010; Oostenbroek et al., 2017; Päkkilä et al., 2015; Pop et al., 2003, 1999; Roman et al., 2013; van Mil et al., 2012). These individual studies showing that maternal hypothyroxinemia is associated with offspring neurodevelopment are also supported by three meta-analyses (including one full systematic review), all of which conclude maternal hypothyroxinemia is associated with increased risk of cognitive delay, intellectual impairment, or lower scores on performance tests when considering the entire body of evidence on this topic [ADDIN EN.CITE ADDIN EN.CITE.DATA]. Additionally, the American Thyroid Association concludes that "overall, available evidence appears to show an association between hypothyroxinemia and cognitive development of the offspring" (Alexander et al., 2017, p. 337).

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[5] For a discussion on the details of the BBDR model, including uncertainties associated with the model the reader is directed to section 3.5 of the MCLG Approaches Report.

The EPA did not conduct a full systematic review and weight of evidence evaluation between maternal thyroid hormones and neurodevelopmental outcomes given: 1) the body of scientific literature regarding this association, and 2) the SAB recommendation that the EPA "consider available data on potential adverse health effects (neurodevelopmental outcomes) due to thyroid hormone level perturbations regardless of the cause of those perturbations" (p. 25). Instead, the EPA conducted a "methodologic approach to reviewing the literature" to evaluate the body of literature on this topic. This approach assisted in extrapolating the relationship modeled by the BBDR model to neurodevelopmental outcomes by concentrating on studies that allowed for evaluation of incremental changes in fT4 as they relate to incremental changes in neurodevelopmental outcomes. More specifically, the EPA only used studies that had sufficient data to show a quantitative relationship between maternal fT4 and a neurodevelopmental outcome. The EPA acknowledges that by not giving any weight to the studies that did not show a quantitative relationship between fT4 and neurodevelopmental outcomes, the Agency may be overestimating the dose of perchlorate that may be associated with adverse neurodevelopmental outcomes. This is a health protective decision that adds to the margin of safety.

Ultimately, the EPA developed a dose-response function that estimates incremental changes in a neurodevelopmental endpoint based on a given change in thyroid hormone concentration (fT4), which could be linked to a given dose of perchlorate using the BBDR model.

The specifics of this "methodologic approach to reviewing the literature" follow. First, the EPA identified and screened the available 71 epidemiological studies, which potentially pertained to altered maternal thyroid hormone levels and offspring neurodevelopment to identify candidates based on the following criteria:

- compatible with the sensitive life stages identified by the NRC and SAB;
- continuous measure of thyroid hormone values (versus categorical values);
- low risk of bias based on analysis using the National Toxicology Program's Office of Health Assessment and Translation (OHAT) Risk of Bias (ROB) tool score; and
- access to underlying data.

Second, using these screening steps, the EPA categorized all 71 studies into three groups. One group consisted of studies that were not compatible[6] with extending the BBDR model (40 studies). Another group consisted of papers that were relevant to the pertinent life stages but did not have data from which a dose-response analysis could be conducted (15 studies). This includes studies that compared differences between groups, for example studies of offspring of mothers with hypothyroxinemia versus offspring of mothers without hypothyroxinemia. Consequently, these studies may have provided insight into the maternal thyroid hormone and offspring neurodevelopment relationship but did not have enough information to develop a

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[6] For example, if the study evaluated the impact of only neonatal thyroid hormones (i.e., at a potentially sensitive life stage), it cannot be used because the BBDR model is specific to early pregnancy. Further, if the study evaluates a population with an existing disease (i.e., hypothyroidism) that may have a different response to perchlorate compared to the euthyroid population, it was not considered compatible with BBDR model results. Additionally, if the study does not include information on T4 or fT4, it does not assist in understanding the implications of the BBDR modeling results. Another reason for exclusion at this stage include that the study does not have a population with an exposure window (i.e., when the thyroid hormone measurements are taken) that overlaps with the outputs for the BBDR model. Specifically, the study should evaluate thyroid hormone levels in pregnant mothers between conception and gestational week 16. The neurodevelopmental outcomes could be measured at any life stage.

continuous dose-response function. The last group of papers had data that may inform a dose-response function (16 studies). This last group of papers included publications that may have had categorical analyses but also presented data that assessed fT4 as a continuous variable and the outcome of interest. In most instances, the continuous fT4 variable encompassed the full range for fT4 and not just the hypothyroxinemic range. After excluding one paper due to a high risk of bias (Kastakina et al., 2006) 15 papers remained that potentially had dose-response data between a continuous measure of fT4 and various neurodevelopmental outcomes describing cognition, behavior and other outcomes. The EPA notes that by selecting the papers that potentially had dose response data the Agency is deviating from the systematic weight of evidence review approach to identify those studies that the SAB recommended we examine to derive the MCLG.

Third, from these 15 papers five were selected for dose response assessment - four related to cognition[ADDIN EN.CITE ADDIN EN.CITE.DATA] and one related to behavior [ADDIN EN.CITE
<EndNote><Cite><Author>Endendijk</Author><Year>2017</Year><RecNum>1915</RecNum><DisplayText>(Endendijk, Wijnen, Pop, & van Baar, 2017)</DisplayText><record><rec-number>1915</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1503500102">1915</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Endendijk, J.J.</author><author>Wijnen, H.A.</author><author>Pop, V.J.</author><author>van Baar, A.L.</author></authors></contributors><titles><title>Maternal thyroid hormone trajectories

during pregnancy and child behavioral problems</title><secondary-title>Horm Behav</secondary-title></titles><periodical><full-title>Horm Behav</full-title></periodical><pages>84-92</pages><volume>94</volume><dates><year>2017</year></dates><urls></urls></record></Cite></EndNote>]. The other ten papers were excluded for a variety of reasons including updated analyses being presented in a different paper for which dose-response analysis was being conducted, lack of all the data needed to complete a dose-response assessment (e.g., dose-response results were presented as "per standard deviation of fT4" but the standard deviation needed to fully interpret the results for a continuous function was not presented in the paper, statistical methods presented in the paper were insufficient to allow for the derivation of a concentration response function), or a lack of a relationship between maternal fT4 as a continuous variable and the outcome of interest evaluated in the paper. For example, Noten et al., (2015) found a relationship between maternal hypothyroxinemia and offspring arithmetic test performance. However, maternal fT4 as a continuous variable across the entire fT4 range was not associated with arithmetic test performance. Given this null finding, as well as the lack of published literature evaluating maternal fT4 as a continuous variable and arithmetic test performance, it would be difficult for the Agency to justify setting an MCLG based on changes in this endpoint.

As laid out for the peer reviewers, for each study that met the criteria identified above for dose-response modeling, a relationship between maternal thyroid hormone levels (specifically fT4) and offspring neurodevelopment was derived (see USEPA, 2018b). These relationships were either presented in the original published paper or derived by the EPA through either the digitization of figures or through re-analysis of data provided by the study authors. The EPA used the upper effect estimate (the upper bound of the 95th percent confidence interval) from each study to assure consideration of the populations likely to be at greater risk from the dose of perchlorate associated with a given change in fT4.

Table III-2 provides a summary of the changes in fT4 predicted to produce a 1, 2, and 3 percent decrease in any given neurodevelopmental effect and corresponding perchlorate doses. The choice of 1, 2, and 3% is based on the analyses for IQ, Mental Development Index (MDI), and Psychomotor Development Index (PDI). Specifically, a 1%, 2%, or 3% change from the standardized mean for each test (i.e., 100 points) equates to a 1, 2, or 3 point change, respectively. The analyses for anxiety/depression score and SD of reaction time are based on a 1%, 2%, or 3% change from the study mean of each measure, which for anxiety/depression is 0.01, 0.02, or 0.03 points, respectively, and for reaction time is 2.7, 5.4, and 8.1 milliseconds (study mean SD of reaction time = 270 ms), respectively (Endendijk et al., 2017; Finken et al., 2013).

These results provide the potential impacts of perchlorate on maternal fT4 (as predicted by the BBDR model) and subsequent neurodevelopmental impacts (derived from the epidemiologic literature[7]).

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[7] For a more complete description of all the studies evaluated the reader is directed to Sections 5 and 6 of the MCLG Approaches Report. For a discussion on the uncertainties related to the approach the reader is directed specifically to section 6.5.

Table III-2. Estimated Dose of Perchlorate per 1, 2, and 3 Percent Decrease[a] in Neurodevelopment for the Population of Low-Iodine Intake Women of Reproductive Age Based on Upper Effect Estimates at the 10th Percentile fT4 Level[b]

Study	Endpoint	Dose-Response Function	β (95% CI)	ΔfT4 in pmol/L Associated with a 1% to 3% Decrease in Endpoint (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 μg/day)[a,b,c]			Dose of Perchlorate per 1% to 3% Decrease in Endpoint (μg/kg/day)[a,b,c]		
				1%	2%	3%	1%	2%	3%
Korevaar et al., (2016) Quadratic	IQ	$\Delta IQ = (\beta_1 \times lnfT4_2 + \beta_2 \times ln(fT4_2)^2) - (\beta_1 \times lnfT4_1 + \beta_2 \times ln(fT4_1)^2)$	β1 = 33.8 (9.8, 57.8) β2 = -6.2 (-10.6, -1.9)	-0.13 (1.9%)	-0.25 (3.8%)	-0.38 (5.7%)	1.9	3.9	6.1
Korevaar et al., (2016) EPA independent analysis	IQ	$\Delta IQ = (\beta_1 \times \ln(fT4_2)) - (\beta_1 \times \ln(fT4_1))$	17.26 (3.77, 30.75)	-0.21 (3.1%)	-0.41 (6.2%)	-0.61 (9.2%)	3.1	6.7	10.8
Pop et al., (2003)	MDI	$\Delta MDI = \beta \times \Delta fT4$	6.3 (1.92, 10.6)	-0.09 (1.0%)	-0.19 (2.8%)	-0.28 (4.2%)	1.3	2.8	4.3
Pop et al., (2003)	PDI	$\Delta PDI = \beta \times \Delta fT4$	8.4 (4.0, 12.8)	-0.08 (0.9%)	-0.16 (2.4%)	-0.23 (3.5%)	1.1	2.3	3.5
Pop et al., (1999)	PDI	$\Delta PDI = \beta \times \Delta fT4$	8.5 (0.01, 17.0)	-0.06 (0.6%)	-0.12 (1.8%)	-0.18 (2.6%)	0.8	1.7	2.6
Endendijk et al., (2017)	Anxiety/ depression score	$\Delta AD = \left(\frac{1}{\beta * fT4_2}\right) - \left(\frac{1}{\beta * fT4_1}\right)$	0.12 (0.11, 0.13)	-0.03 (0.45%)	-0.08 (1.2%)	-0.12 (1.9%)	0.4	1.1	1.8
Finken et al., (2013)	SD of reaction time	ΔSD Reaction Time (ms) = β × Δ fT4	-4.9 (-9.5, -0.2)	-0.28 (4.2%)	-0.57 (8.5%)	-0.85[d] (12.7%)	4.4	9.8	16.5[d]

Study	Endpoint	Dose-Response Function	β (95% CI)	ΔfT4 in pmol/L Associated with a 1% to 3% Decrease in Endpoint (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 μg/day)[a,b,c]			Dose of Perchlorate per 1% to 3% Decrease in Endpoint (μg/kg/day)[a,b,c]		
				1%	2%	3%	1%	2%	3%

[a]. The analyses for IQ, Mental Development Index (MDI), and Psychomotor Development Index (PDI) are based on a 1%, 2%, or 3% change from the standardized mean for each test (i.e., 100 points), which equates to a 1, 2, or 3 point change, respectively. The analyses for anxiety/depression score and SD of reaction time are based on a 1%, 2%, or 3% change from the study mean of each measure, which for anxiety/depression is 0.01, 0.02, or 0.03 points, respectively, and for reaction time is 2.7, 5.4, and 8.1 milliseconds (study mean SD of reaction time = 270 ms), respectively.
[b]. This is based on the regression analysis for the range of fT4 data within each study using the upper beta estimates from the 95% CI. These results are for the low-iodide intake population of 75 μg/day. In all functions, fT4 is in units of pmol/L.
[c]. The BBDR model with a pTSH of 0.398 was used for these analyses.
[d]. The value which results in a 3% change in the standard deviation of reaction time falls between 16 and 17 μg/kg/day. Because data was not available on the changes of fT4 at doses between 16 and 17 μg/kg/day perchlorate, the EPA took the midpoint of the range of values for the change in fT4 at 16 and 17 μg/kg//day and assumed the dose of perchlorate associated with this change was the midpoint between 16 and 17 μg/kg/day.

H. Identifying a Point of Departure for Developing the MCLG

From the seven analyses presented in Table III-2 above, the EPA chose to use its independent analysis of the Korevaar et al., (2016) data (comprising of 3,600 useable mother/child data pairs) as the basis for calculating the point of departure (POD) for the MCLG. There are three reasons for this selection: 1) there is sufficient quantitative data to derive a health impact function for the sensitive population of interest; 2) the analysis adjusts for an appropriate set of confounders, and 3) the neurodevelopmental endpoint – intelligence quotient (IQ) – is more straightforward to interpret because there is more national and cross-national data available (more on the selection of this endpoint below). The other studies presented in Table III-2 do not provide one or more of these features (USEPA, 2018b).

The five identified papers evaluated a variety of endpoints with Korevaar et al., (2016) evaluating IQ, Pop, Kuijpens, et al., (1999) and Pop, Brouwers, et al., (2003) using the Bayley Scale to evaluate PDI and MDI, Finken, van Eijsden, Loomans, Vrijkotte, and Rotteveel (2013) evaluating the SD of reaction time, and Endendijk, Wijnen, Pop, and van Baar (2017) evaluating anxiety/depression scores using the Child Behavioral Check List (CBCL). The SD of reaction time from Finken et al., (2013) was not well-received by the peer reviewers (External Peer Review for U.S. EPA, 2018) because it is difficult to ascertain the true implications of a change in the SD of reaction time. The Endendijk et al., (2017) study was identified after the peer review so no feedback was given on the appropriateness of the endpoint; however, the anxiety/depression raw score is not an intuitively interpretable endpoint. Further, neither the Endendijk et al., (2017) nor the Finken et al., (2013) analyses had functions for the sensitive life stage (i.e., their analyses were based on the full range of fT4 levels and did not concentrate on the impacts of low-end fT4 levels). For these reasons, the Endendijk et al., (2017) and Finken et al., (2013) papers were not selected for further evaluation.

The Korevaar et al., (2016) original and independent analyses are preferable compared to the Pop, Kuijpens, et al., (1999) and Pop, Brouwers, et al., (2003) studies because neither function derived from the Pop et al., studies was adjusted for confounders. Additionally, both Pop et al., papers have an N < 50 compared to the Korevaar et al., analyses, which have an N of greater than 3,600.[8]

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[8] The original Korevaar et al. (2016) analysis included 3,839 mother/child pairs. The EPA reanalysis of the Korevaar et al. (2016) data had a slightly lower N of 3,609 due to the exclusion of subjects with imputed values for maternal fT4.

Although the original Korevaar et al., (2016) analysis was the most rigorous analysis available in the literature to date, the Korevaar et al., (2016) EPA reanalysis was chosen over the original analysis because it included modifications to the analysis at the suggestion of the peer review panel. The revised analysis controls for a more parsimonious set of confounders (e.g., previously included variables such as infant gender, maternal parity, birthweight, mother's body mass index (BMI), and gestational age at blood draw that are not related to both the exposure and the outcome were excluded), thus decreasing the chances of overfitting the estimation of the association between maternal fT4 and child IQ. The EPA was prompted to revisit the original Korevaar et al., (2016) model because of the feedback received during the peer review of the MCLG Approaches Report. Specifically, a member of the peer-review panel expressed the following suggestion:

> *Korevaar et al., [2016] controlled for instrumental variables (e.g. gestational week at fT4 measurement) as well as variables that are consequences of altered fT4 (e.g. maternal BMI), which may have biased estimates. This study also assumed a log-linear relation between fT4 and the outcome but it is unclear whether the data fit this functional form better than a linear form. Reanalysis of the data performed by EPA should not include the variables noted above, which may have driven measures of association towards the null, and should investigate the most appropriate functional form to inform decisions about transformation of fT4 values* (External Peer Reviewers for U.S. EPA, 2018, pp. 61–62).

The EPA responded to this suggestion by developing a causal model for the effect of maternal fT4 on child IQ to identify the minimum set of confounding variables, testing the proper functional form of the relationship between maternal fT4 and child IQ in the Korevaar et al., (2016) data, and making decisions about data quality and influential data points in the analysis. That is, the EPA determined that there were values of the independent variable of interest, fT4, in the original analysis that were imputed using multiple imputations. This could have impacted the effect estimate of the independent variable of interest with data that were not directly measured. The EPA reanalysis excludes these non-measured values. Subsequently, the EPA selected the Korevaar et al., (2016) reanalysis as the most appropriate function from which to assess the relationship between fT4 and IQ [9].

As indicated above, the EPA has utilized a health protective approach to this analysis consistent with the SDWA definition of the MCLG. The peer reviewers commented that this approach was fit-for-purpose. In particular, the Agency assumed it could estimate risk reductions based on evidence of a quantifiable relationship between thyroid hormone changes and neurodevelopmental outcomes. The existence of a quantifiable relationship between thyroid hormone changes and neurodevelopmental outcomes has strong support from the literature on the subject; however, not every study identified an association between maternal fT4 and the specified outcome of interest, and the state of the science on this relationship is constantly evolving. As explained earlier, the results of the EPA's dose-response literature review identified

[9] A more complete description of the EPA independent analysis of the Korevaar et al. (2016) data can be found in Section 6.3.2 of the MCLG Approaches Report.

31 studies that evaluated the association between maternal thyroid hormone levels and offspring neurodevelopment, with neurodevelopment defined using a variety of endpoints related to cognition, behavior, and other outcomes such as autism. Among these studies, only 16 were deemed to potentially possess information that could inform a dose-response relationship. The other 15 only presented data on categorical analyses assessing the impact of maternal hypothyroxinemia on the neurodevelopmental outcomes of interest. Therefore, because the data presented was only a comparison of two groups, there was not information that could be used to inform a dose-response function.

Of the 16 studies that potentially had data to inform a dose-response function, 10 evaluated cognition using a variety of tests including various IQ tests (three papers; Ghassabian et al., 2014; Korevaar et al., 2016; Moleti et al., 2016), Bayley Scales of Infant Development (two papers; Pop et al., 1999; Pop et al., 2003), and other validated tests associated with child cognition such as expressive language delay or test performance (five papers; Finken et al., 2013; Henrichs et al., 2010; Kastakina et al., 2006; Noten et al., 2015; Oken et al., 2009). Six of these papers found a statistically significant relationship between maternal fT4, as a continuous variable, and offspring cognitive outcome (Korevaar et al., 2016; Pop et al., 1999; Pop et al., 2003; Finken et al., 2013; Henrichs et al., 2010, Kastakina et al., 2006). However, there were studies where maternal fT4 as a continuous variable was not significantly associated with the outcome of interest. For example, in Ghassabian et al., (2014) the authors found maternal hypothyroxinemia to be associated with an average of a 4.3-point reduction in IQ in their offspring compared to offspring of non-hypothyroxinemic mothers. Nevertheless, when assessing the relationship between the continuous measure of maternal fT4 as a continuous variable (across the entire range of fT4 levels) and child IQ, the authors did not find a significant relationship. Additionally, Moleti et al., (2016) found the relationship between maternal fT4 and child IQ to be consistently inversely associated with IQ scores, but their assessment failed to reach statistical significance. This study included fewer than 60 study participants and was considered by the authors to be a pilot assessment.

In addition to the cognitive effects assessed and modeled, the EPA identified four papers that assessed maternal fT4 status and behavioral outcomes (Endendijk et al., 2017; Ghassabian et al., 2011; Modesto et al., 2015; Oostenbroek et al., 2017), one paper that assessed maternal fT4 status and autism (Roman et al., 2013) and one paper that evaluated odds of a schizophrenia diagnosis as associated with maternal thyroid hormone status (Gyllenberg et al., 2016). From this group of papers, the majority of papers found an association either between maternal hypothyroxinemia or maternal fT4 as a continuous variable and the outcome of interest (Endendijk et al., 2017; Modesto et al., 2015; Oostenbroek et al., 2017; Roman et al., 2013; Gyllenberg et al., 2016). However, this was not always the case as exemplified by Ghassabian et al., (2011) and Gyllenberg et al., (2016). Although Endendijk et al., (2017) found maternal fT4 to have a significant adverse impact on anxiety/depression using the Child Behavioral Check List (CBCL), Ghassabian et al., (2011) did not find any association between maternal thyroid hormone status and offspring score on various components of the CBCL. Additionally, Gyllenberg et al., (2016) found maternal hypothyroxinemia during early to mid-gestation was associated with 70% increased odds of schizophrenia diagnosis in offspring of hypothyroxinemic mothers compared to the offspring of non-hypothyroxinemic mothers. Gyllenberg et al., (2016) also found an association with odds of schizophrenia diagnosis using conditional logistic regression when assessing fT4 as a continuous variable across the entire fT4 range (i.e., not just the hypothyroxinemic range); however, this relationship was attenuated after controlling for smoking.

Not every paper the EPA located in its literature review found a statistically significant association between maternal fT4 as a continuous variable (i.e., the initially identified 16 studies identified as potentially useful to inform a dose-response function) and the neurodevelopmental outcome of interest. However, many studies located in the EPA literature review, several meta-analyses ([HYPERLINK \l "_ENREF_47" \o "Fan, 2016 #307"]; Thompson et al., 2018 and [HYPERLINK \l "_ENREF_187" \o "Wang, 2016 #327"]), the American Thyroid Association (Alexander et al., 2017) and the U.S. EPA's SAB (2013) have concluded there is a relationship between maternal hypothyroxinemia and various neurodevelopmental outcomes. The relationship between maternal fT4 levels and neurodevelopmental outcomes appears strongest in the hypothyroxinemic range, and when looking at the entire range of fT4 as a continuous variable (as opposed to a categorical cut off), the significant relationship between the two variables may dissipate. Therefore, the EPA has concentrated on the neurodevelopmental impacts of changes in fT4 in the lower range of fT4 from the Korevaar et al., (2016) data. In an attempt to minimize uncertainty, the EPA reanalyzed the data collected by Korevaar et al., (2016) using a spline function that estimates a coefficient specifically for the low range of the fT4 data.

There are a variety of neurodevelopmental endpoints used to examine behavior and cognition in children (e.g., intelligence quotient (IQ), motor skills, vocabulary and language development, stimulus responsiveness, etc.). The EPA selected IQ decrements because this was the endpoint evaluated in the Korevaar et al., (2016) study. The EPA determined that the Korevaar study was the most rigorous analysis that examined the relationship between decreased thyroid hormones and neurodevelopmental effects. As such, in the derivation of the MCLG, IQ is a surrogate for a suite of potential neurodevelopmental effects that might occur to the offspring of hypothyroxinemic and iodine deficient mothers.

There are several different tests that are widely used to measure IQ in children, including the Stanford-Binet and the Wechsler Intelligence Scale for Children (WISC) (Sternberg et al., 2001). Each of these tests is intended to assess a child's global functioning and uses a numerical IQ point scale (Beres et al., 2000). IQ scores are standardized by age and sex group with a mean score of 100 points and a standard deviation of 15 (Beres et al., 2000). Although the specific tasks differ by test, all IQ tests contain a number of tasks to assess diverse skills (Sternberg et al., 2001). For example, the WISC test evaluates full-scale IQ using a combination of verbal and performance scales (verbal IQ and performance IQ may also be assessed separately) (Beres et al., 2000). The verbal scale includes tasks such as arithmetic, vocabulary, and comprehension, while the performance scale includes tasks such as picture completion, block design, and object assembly (Beres et al., 2000). The WISC was standardized using a sample of 2200 U.S. children aged 6 to 16 years old (Seashore et al., 1950). It has been well validated and has demonstrated high reliability, with a reliability coefficient of 0.96 observed across age groups (Beres et al., 2000).

Associations have been found between IQ scores and both educational achievement and attainment, though observed correlations vary widely. In a review of the literature, Sternberg et al., (2001) suggest that IQ scores explain approximately 25% of the variance in academic achievement. Evidence also suggests that IQ is linked to career outcomes and job performance, with observed correlations ranging from approximately 0.2 to 0.6 (Sternberg et al., 2001). Research suggests that children's rearing environment, including parental education, while growing up may increase IQ scores in adolescence by several points (e.g., Kendler et al., 2015).

IQ scores have been used to help diagnose disorders such as intellectual disability and to identify children for placement into specialized learning programs (Beres et al., 2000). For example, in the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-V) IQ scores are used in an individual's comprehensive assessment to determine intellectual disability, which pairs standardized testing of intelligence with a clinical assessment of adaptive functioning. Intellectual disability is considered for individuals with an IQ score of about 70 or below (American Psychiatric Association, 2013).

The EPA uses a variety of science policy approaches to select points of departure for developing regulatory values. For instance, in noncancer risk assessment the EPA often uses a percentage change in value. When assessing toxicological data, a 10 percent extra risk (for discrete data), or a 1 standard deviation (i.e., 15 IQ points) change from the mean (for continuous data) is often used (USEPA, 2012). A smaller response to inform a POD has been applied when using epidemiological literature because there is an inherently more direct relationship between the study results and the exposure context and health endpoint. Given the difficulty in identifying a response below which no adverse impact occurs when considering a continuous outcome in the human population, the EPA looked to its Benchmark Dose Guidance (2012) for insight regarding a starting point. Specifically, "[a] BMR of 1% has typically been used for quantal human data from epidemiology studies" (p. 21, USEPA, 2012).

For the specific context of setting an MCLG for perchlorate, the EPA made a policy decision to evaluate the level of perchlorate in water associated with a 1 percent decrease, a 2 percent decrease, and a 3 percent decrease in population IQ. The EPA selected IQ as a surrogate for neurodevelopmental effects based upon its evaluation of the epidemiologic literature describe above. The need to utilize the best available peer reviewed data to inform scientific assumptions and policy choices to meet the statutory requirements associated with developing an MCLG under the SDWA highlights the challenges associated with regulating chemicals for which potential effects are indirect, and scientific data do not address all uncertainties. The Agency must make a policy decision informed by science, consistent with statutory requirements even in situations where the data do not provide clear choices. In this case, the EPA made a policy decision to use a 2 IQ point decrement to develop the proposed MCLG for perchlorate. By selecting this approach, the EPA is not establishing a precedent for future Agency actions on other contaminants for which there is concern about potential thyroid effects, either under the SDWA or other statutory frameworks.

Applying these response rates to the results from the reanalysis of Korevaar et al., (2016), results in a POD dose of 3.1 μg/kg/day for a 1 percent decrease in the population's IQ, a POD dose of 6.7 μg/kg/day for a 2 percent decrease in the population's IQ, and a POD dose of 10.8 μg/kg/day for a 3 percent decrease in the population's IQ. These PODs associated with a 1, 2, or 3 percent decrease from the standardized mean IQ are calculated for the most sensitive population. Specifically, the POD is designed to provide an adequate margin of safety for the fetuses of mothers with fT4 at the 10^{th} percentile of a population with iodine intake of 75 μg/day and a TSH feedback loop that is less than 60% as effective as individuals with median TSH feedback loop efficacy. That is, the analysis is designed to protect the population of fetuses of mothers with suboptimal thyroid functioning. For these reasons, and for the methodological reasons described previously, the EPA believes that the selection of these parameters and this point of departure assures no known or anticipated adverse effects on the health of the most sensitive population and allows for an adequate margin of safety.

I. Translate PODs to RfDs

When deriving an RfD the EPA evaluates whether to apply uncertainty/variability factors to account for heterogeneity of effect in the target population and data gaps (USEPA, 2002). As presented in *A Review of the RfD & RfC Processes* (USEPA, 2002) the EPA considers the following uncertainty factors: inter-individual variability, interspecies uncertainty, extrapolating from subchronic to chronic exposure, extrapolating from a lowest-observed adverse effect level (LOAEL) rather than from a no-observed-adverse-effect-level (NOAEL), and an incomplete database. The factors are intended to account for: 1) variation in susceptibility among the members of the human population (i.e., inter-individual or intraspecies variability); 2) uncertainty in extrapolating animal data to humans (i.e., interspecies uncertainty); 3) uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); 4) uncertainty in extrapolating from a LOAEL rather than from a NOAEL; and 5) uncertainty associated with extrapolation when the database is incomplete. (U.S. EPA, 2011b) The EPA has considered each of these factors in deriving an RfD to inform an MCLG for perchlorate.

The EPA considered variation and uncertainty in the relationship between exposure and response among the members of the human population (i.e., uncertainty factor (UF) for within-human variability/ inter-individual variability, UF_H). For this analysis a UF of 3 is used. The approach taken to derive the RfD attempts to address variability between the general population and the sensitive population. Specifically, the EPA was able to modify the strength of the TSH feedback loop and iodine intake levels in the BBDR model and concentrate on the dose-response relationship between lower level (as opposed to median level) fT4 and neurodevelopmental outcomes. However, there is still uncertainty in the relationship between perchlorate exposure and subsequent neurodevelopmental outcomes[10]. There are very few toxicokinetic calibration data available for the perchlorate to thyroid hormone relationship described in the BBDR model. On the toxicodynamic side of the BBDR model, aspects such as competitive inhibition at the NIS, depletion of iodide stores under different iodine intake levels and physiological states, and

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[10] For a more complete discussion on the uncertainties in the analysis the reader is directed to Sections 3.5 and 6.5 of the MCLG Approaches Report.

the ability of the TSH feedback loop to compensate for perturbations in thyroid function each have their own uncertain features. There are also uncertainties linking maternal fT4 levels to offspring IQ. These uncertainties include the population for which dose-response information is available (i.e., no study is U.S. based), a lack of study information on the iodine intake status for the population for which the dose-response information is available, uncertainties around the methods used to assess maternal fT4 measurement during pregnancy, and uncertainties related to the true distribution of fT4 for a given iodine intake.

Further, as discussed in section III.C. of this notice the EPA believes that protecting the fetus of a hypothyroxinemic woman will protect other identified sensitive life stages. However, there is some uncertainty due to the lack of information linking incremental changes in infant thyroid hormone levels to adverse neuorodevelopmental outcomes. In addition, this analysis is assuming that protecting a first trimester fetus from alterations in maternal fT4 will protect the fetus throughout pregnancy. This is based on epidemiologic evidence that shows the relationship between first trimester maternal fT4 and neurodevelopmental outcomes. This is potentially because before mid-gestation, the mother is the only source of thyroid hormone for the fetus (Morreale de Escobar et al., 2004). Therefore, when evaluating maternal fT4 as associated with neurodevelopmental outcomes it is critical to understand the first-trimester levels. Later in gestation, when the fetal thyroid begins secreting thyroid hormones, maternal fT4 may no longer be a good surrogate for the thyroid hormone levels available to the fetus. Given that the fetal thyroid has had little time to develop, its iodine storage is much less than that of an adult, hence there may be more sensitivity to short-term fluctuations in iodine availability and uptake that may have little impact on maternal levels. Therefore, there is some uncertainty about the impact perchlorate may have on the fetal thyroid gland, and subsequent neurodevelopmental impacts, in later trimesters of pregnancy. The immature fetal HPT axis has very limited capacity to increase output of thyroid hormones (Savin, Cvejić, Nedić, & Radosavljević, 2003; van Den Hove, Beckers, Devlieger, De Zegher, & De Nayer, 1999), so the fetal HPT may not be able to adjust output in the face of reduced maternal fT4 supply and perchlorate exposure. Therefore, as described above, the EPA selected an intraspecies UF of 3 to account for the uncertainties in modeling the impacts of perchlorate ingestion on the thyroid hormone levels for pregnant mothers with low iodide intake, and the uncertainties in predicting the neurodevelopmental effects of these thyroid hormone changes on their children.

The EPA considered but did not derive a Data-Dependent Extrapolation Factor (DDEF) for this analysis. As described above, the UFs are applied based on the uncertainties in the perchlorate to thyroid hormone and thyroid hormone to neurodevelopment relationship[11]. As noted above, the Agency has opted to apply a UF of 3 to the POD, which adds an adequate margin of safety to the MCLG derivation. Section 4.4.5.3 (p 4-42) of *A Review of the RfD & RfC Processes* recommends reducing the intraspecies UF from a default of 10 "only if data are sufficiently representative of the exposure/dose-response data for the most susceptible subpopulation(s)" (p. xviii, USEPA, 2002).The EPA selected a UF of 3 instead of the full 10 because the modeled groups within the population that are identified as likely to be at greater risk

[11]As explained in U.S. EPA, 2014 "UFs incorporate both extrapolation components that address variability (heterogeneity between species or within a population) and components that address uncertainty (i.e., lack of knowledge)…whereas DDEFs focus on variability" (p. 7, US EPA, 2014).

to perchlorate in drinking water (i.e., the fetus of the iodide deficient pregnant mother) and has selected model parameters to account for the most sensitive individuals in that group (i.e., muted TSH feedback, low fT4 values, low-iodine intake).

Below we list the other uncertainty factors added and the justification.

- Uncertainty in extrapolating animal data to humans (i.e., interspecies uncertainty) (uncertainty factor, animal-to-human, UF_A). For this analysis an UF of 1 is used because this factor is not applicable since animal studies were not used to develop the BBDR model nor were they used to relate alterations in maternal fT4 to IQ.
- Uncertainty in extrapolating data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure, UF_S). An uncertainty factor of 1 is used. Extrapolating from subchronic to chronic exposures did not occur as the BBDR model was designed to assess long-term steady-state conditions in the non-pregnant woman and week-to-week variation in pregnancy, rather than short-term (hour-to-hour or day-to-day) fluctuations.
- Uncertainty in extrapolating from a LOAEL rather than from a NOAEL (uncertainty factor, LOAEL-to-NOAEL, UF_L). A more sophisticated BBDR modeling approach, coupled with extrapolation to changes in IQ using linear regression, was used to determine a POD that would not be expected to represent an adverse effect. Subsequently an uncertainty factor of 1 is used. LOAELs and NOAELs were not identified or used in this approach.
- Uncertainty factor for database deficiency to address the potential for deriving an inadequately protective RfD in the instance where the available database provides an

incomplete characterization of the chemical's toxicity (database deficiency, UF_D; USEPA, 2002). An uncertainty factor of 1 is used as "[t]he mode of action of perchlorate toxicity is well understood" (SAB for the U.S. EPA, 2013, p. 2).

- The product of all the uncertainty factors (UF_H) is 3 (3 x 1 x 1 x 1 x 1).

Below we generate RfD's for each of the points of departure.

Using the POD of 6.7 µg/kg/day based on a 2 percent decrease in the population standardized mean IQ from the EPA's independent analysis of the Korevaar et al., (2016) data, the EPA can derive a RfD by incorporating the UF_H, which results in the following:

$$RfD = \frac{POD}{UF_H} = \frac{6.7}{3} = 2.2\ \frac{\mu g/kg}{day}$$

Using an alternative POD of 3.1 µg/kg/day based on a 1 percent decrease in the population standardized mean IQ from the EPA's independent analysis of the Korevaar et al., (2016) data, the EPA can derive an RfD by incorporating the UF_H. This results in the following:

$$RfD = \frac{POD}{UF_H} = \frac{3.1}{3} = 1.0\ \frac{\mu g/kg}{day}$$

Using an alternative POD of 10.8 µg/kg/day based on a 3 percent decrease in the population standardized mean IQ from the EPA's independent analysis of the Korevaar et al., (2016) data, the EPA can derive an RfD by incorporating the UF_H. This results in the following:

$$RfD = \frac{POD}{UF_H} = \frac{10.8}{3} = 3.6\ \frac{\mu g/kg}{day}$$

J. Translate RfD into an MCLG

To translate the RfD (µg/kg/day) to a concentration in drinking water (µg/L), the EPA used the following equation:

$$W\left(\frac{\mu g}{L}\right) = \frac{RfD}{DWI} \times RSC_w$$

where:

W = drinking water concentration of perchlorate in micrograms per liter (µg/L);

RfD = reference dose (1.03 µg/kg/day for a 1 percent decrease in IQ, 2.23 µg/kg/day for a 2 percent decrease in IQ, or 3.6 µg/kg/day for a 3 percent decrease in IQ);

DWI = bodyweight-adjusted drinking water ingestion rate (L/kg/day); and

RSC_w = relative source contribution of drinking water to overall perchlorate exposure.

To calculate the MCLGs, the EPA selected the 90th percentile body-weight adjusted drinking water ingestion rate specific to women of childbearing age (i.e., non-pregnant, non-lactating, 15–44 years of age (0.032 L/kg/day). This decision is consistent with the analysis used in deriving an RSC, which was performed using food consumption information for a population of women of childbearing age from NHANES. The 90th percentile is chosen to account for variability in drinking water ingestion rates, but also adds another layer of health protection for 90% of women (Table III-3).

The EPA did not use water intake data for pregnant women because the sample sizes were too small to be statistically stable. The use of the drinking water intake for 15-44 year old women is consistent with the analysis used in deriving an RSC_w (described below), which was performed using food consumption information for a population of women of childbearing age from NHANES. The EPA acknowledges there is a difference in the age range defining women of childbearing age used to develop the drinking water ingestion rate and that used to develop the RSC (20 – 44 years of age). The age range used to develop the RSC was based on the range of ages used to define women of childbearing age in developing the BBDR model. However, the EPA's Exposure Factors Handbook (USEPA, 2011c) identifies drinking water ingestion rates for women 15-44 years of age as corresponding to women of childbearing age.

The age range used for women of childbearing age in the BBDR model fits within the age range used to develop the ingestion rates provided in the Exposure Factors Handbook. Thus, the Agency believes the difference in the age ranges will have minimal impact on the resulting MCLG analysis.

Table III-3. Consumers-Only Estimated Direct and Indirect Community Water Ingestion Rates from Kahn and Stralka (2008) (L/kg/day)

Female Population Categories	Sample Size	Mean	90th Percentile	95th Percentile
Pregnant	65	0.014[a]	0.033[a]	0.043[a]
Lactating	33	0.026[a]	0.054[a]	0.055[a]
Non-pregnant, non-lactating, 15 to 44 years of age	2,028	0.015	0.032	0.038
[a] The sample size does not meet minimum reporting requirements to make statistically reliable estimates as described in the *Third Report on Nutrition Monitoring in the United States*, 1994-1996 (FASEB/LSRO, 1995).				

Individuals are exposed to perchlorate through ingestion of both food and drinking water (ATSDR 2008, Huber et al., 2011). In calculating the MCLGs, the EPA applies a relative source contribution (RSC) to the RfD to account for the percentage of the RfD remaining for drinking water after other sources of exposure to perchlorate have been considered. Thus, the RSC for drinking water is based on the following equation where "Food" is the perchlorate dose from food ingestion:

$$RSC = \frac{RfD - Food}{RfD} \times 100\%$$

To estimate the dose of perchlorate for women of childbearing age coming from food, the EPA implemented a data integration methodology that combined demographic variables, food consumption estimates, and perchlorate contamination estimates in food from multiple sources (USEPA, 2019c). These sources include:

- The NHANES data available from the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) including the What We Eat in America (WWEIA) 24-hour food diary data (CDC & NCHS, 2007, 2009, 2011); and
- The Food and Drug Administration's (FDA's) Total Diet Study (TDS) (U.S. Food and Drug Administration (FDA), 2015), which analyzes contaminants in about 280 kinds of food and beverages commonly consumed by the U.S. population.

The NHANES data provided individual food consumption profiles for female participants age 20-44 (the women of childbearing age range used for the BBDR model). The EPA matched TDS perchlorate concentrations with each food consumed by a participant and calculated each participant's daily perchlorate dose (µg/kg/day) from food using the participant's body weight. The EPA estimated each participant's perchlorate dose using both mean and 95th percentile perchlorate concentrations in food. The details of these assumptions are explained on page 5-5 of the Technical Support Document: Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water (USEPA 2019c). Specifically, the EPA calculated both the mean and the 95th percentile of the perchlorate levels in each food based on the 20 samples included in the TDS data. In order to estimate the 95th percentile from the 20 samples, the EPA used the second-highest test result for each food to represent the 95th percentile concentration. While simple, this method avoids the need to assume a distributional shape for the samples, and has been used in recent publications of TDS data for iodine [ADDIN EN.CITE <EndNote><Cite><Author>Carriquiry</Author><Year>2016</Year><RecNum>2008</RecNum><DisplayText>(Carriquiry et al., 2016)</DisplayText><record><rec-number>2008</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1530039524">2008</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Carriquiry, A. L. </author><author>Spungen, J. H.</author><author>Murphy, S. P.</author><author>Pehrsson, P. R.</author><author>Dwyer, J. T.</author><author>Juan, W.</author><author>Wirtz, M. S. </author></authors></contributors><titles><title>Variation in the iodine concentrations of foods: considerations for dietary assessment</title><secondary-title>The American Journal of Clinical Nutrition</secondary-title></titles><periodical><full-title>The American Journal of Clinical Nutrition</full-title></periodical><pages>877S–887S</pages><volume>104</volume><number>Suppl 3</number><dates><year>2016</year></dates><urls></urls></record></Cite></EndNote>]. The aforementioned method for identifying the 95th percentile concentration of perchlorate from food was selected over other, more “statistically based” methods for estimating percentiles as it avoids the need to assume a distributional shape for the samples. The EPA determined that it was more reliable to assume the empirically derived distribution as the basis for selecting the 95th percentile (i.e., assuming the distribution was equal to the distribution of samples collected in the TDS), as opposed to forcing a distributional shape, such as normal or log-normal, onto the data that may not necessarily be appropriate. With the chosen method, we can at least be sure that the distributional shape is appropriate for the data at hand, whereas by choosing the alternative that assumes a distributional shape, in many instances we would not even be certain of that. The EPA used these individual bodyweight-adjusted perchlorate doses from food to calculate distributions of perchlorate dose from food for the population of women age 20-44.

Table III-4 presents the mean and selected percentiles of the distribution of perchlorate dose from food for women ages 20-44, for both mean and 95th percentile perchlorate concentrations in food based on the TDS. To calculate the RSC, the EPA selected the 90th percentile dose of perchlorate from food, assuming a scenario where the food contained the 95th percentile perchlorate concentration. This corresponds to a perchlorate dose for food of 0.45 μg/kg/day. The EPA chose to use the 90th percentile bodyweight-adjusted perchlorate consumption from food using the 95th percentile TDS results to estimate the perchlorate RSC from drinking water. The EPA believes this is the most appropriate value for perchlorate consumption from food to ensure the protection of potentially highly exposed individuals. Given the range of perchlorate concentrations in food, and that food is the only other exposure source being considered in the RSC analysis, the EPA believes it is sufficiently protective to estimate the MCLG for drinking water using the 90th percentile bodyweight-adjusted perchlorate consumption based on the 95th percentile perchlorate food concentrations in TDS. This assures that highly exposed individuals from this most sensitive population are considered in the evaluation of whether perchlorate is found at levels of health concern.

Table III-4. Perchlorate Dose from Food (µg/kg/day) in U.S. Women Ages 20-44 using the mean and 95th Percentile TDS Results[1]

Level of Bodyweight Adjusted Perchlorate Consumption from Population Distribution	Perchlorate Dose from Food (µg/kg/day)	
	Based on Mean Concentrations of Perchlorate in Food	Based on 95th Percentile Concentrations of Perchlorate in Food
Mean	0.09 – 0.12	0.23 – 0.24
50th Percentile	0.08 – 0.10	0.17 – 0.19
90th Percentile	0.18 – 0.21	**0.45**
99th Percentile	0.33 – 0.38	1.16 – 1.17

[1] Ranges are due to various approaches for handling values <level of detection. If no range is presented all approaches resulted in the same value.
Bolded value represents the selected value

The EPA used the drinking water intake and perchlorate dose from food to calculate MCLGs for the three RfD values. Table III-5 shows the RSC values for the three RfD values and the corresponding MCLGs calculated using the EPA's standard equation.

Table III-5. Estimates for RSC and MCLG by RfD

RfD[a] (µg/kg/day)	RSC_W[b] (percent)	DWI (L/kg/day)	MCLG[c] (µg/L)
1.0	56%	0.032	18
2.2	80%	0.032	56
3.6	80%[d]	0.032	90

a. The RfD values corresponding to protecting the fetus of a first trimester pregnant mother with low-iodine intake levels (i.e., 75 µg/kg/day), low fT4 levels (i.e., 10th percentile of a fT4 distribution for individuals with 75 µg/day iodine intake), and weak TSH feedback strength (i.e., TSH feedback is reduced to be approximately 60 percent less effective than for the median individual) from either a 1-point IQ loss, 2-point IQ loss, or a 3-point IQ loss, respectively.

b. The EPA calculated RSC values based on the following equation given a Food intake of 0.45 µg/kg/day:

$$RSC = \frac{RfD - Food}{RfD} \times 100\%$$

c. The EPA calculated the MCLG values based on the following equation given the respective RfD and RSC values and the DWI:

$$W\left(\frac{\mu g}{L}\right) = \frac{RfD}{DWI} \times RSC_w$$

d. The calculated RSC value using the equation in footnote b is 88 percent. However, the EPA has opted to follow previously established recommendations which employs a ceiling of 80 percent for the RSC value (USEPA 2000d).

IV. Maximum Contaminant Level Goal and Alternatives

Section 1412(a)(3) of the SDWA requires the EPA to propose a maximum contaminant level goal (MCLG) simultaneously with the NPDWR. The MCLG is defined in Section 1412(b)(4)(A) as "the level at which no known or anticipated adverse effects on the health of persons occurs and which allows an adequate margin of safety." The EPA is proposing an MCLG of 56 μg/L based on the rationale and methodology described in Section III above. The derivation of the proposed MCLG uses a point of departure based upon a two percent decrease in IQ for offspring of hypothyroxinemic women of child bearing age have with low iodine intake. The EPA selected a 2 percent decrease in IQ for the proposed perchlorate MCLG because this represents a small change in IQ, well below one standard deviation for the subpopulation of interest.

As described in Section III, the EPA has selected model parameters and other factors for the derivation of the MCLG that are health protective, including the focus on the most sensitive life stage. The EPA believes that the selection of the combination of protective parameters and this point of departure assures no known or anticipated adverse effects on the health of the most sensitive subpopulation and allows for an adequate margin of safety. The EPA also acknowledges the uncertainties in the derivation of the proposed (and alternative) MCLGs. The EPA acknowledges in particular the challenge associated with selecting the decrement of IQ that represents an adverse effect at the population level and the uncertainties in predicting the dose of perchlorate that may result in a particular IQ decrement given the absence of robust human epidemiological data directly linking perchlorate exposure to IQ decrements. The Agency seeks comment on the alternative MCLG values of 18 μg/L and 90 μg/L, which the EPA derived using the methodology described in Section III based on a one percent and three percent decrease in IQ, respectively.

V. Maximum Contaminant Level and Alternatives

Under section 1412(b)(4)(B) of the SDWA, the EPA must establish a maximum contaminant level (MCL) as close to the MCLG as is feasible. The EPA evaluated available analytical methods to determine the lowest concentration at which perchlorate can be measured and evaluated the treatment technologies for perchlorate that have been examined under field conditions (USEPA 2018a, 2019b). The EPA determined that setting an MCL equal to the proposed MCLG of 56 μg/L is feasible given that the approved analytical method for perchlorate for UCMR 1 has a minimum reporting level (MRL) of 4 μg/L (USEPA 1999, 2000c) and that available treatment technologies can treat to concentrations well below 56 μg/L (USEPA, 2018c). Therefore, the EPA is proposing to set the MCL for perchlorate at 56 μg/L.

Because the EPA is taking comment on alternative MCLG values of 18 μg/L and 90 μg/L the Agency evaluated the feasibility of setting an MCL at these levels. The EPA determined that the proposed MCL of 56 μg/L is feasible, therefore a higher MCL alternative such as 90 μg/L is also feasible. The EPA has concluded that analytical methods are capable of measuring perchlorate at 18 μg/L and that treatment technologies have been demonstrated to achieve this level under field conditions (USEPA 2018a, 2019b). Therefore, the EPA is requesting comment on the feasibility of the proposed MCL of 56 µg/L as well as the feasibility of the alternative MCLs of 18 µg/L and 90 µg/L.

As the occurrence analysis in section VI demonstrates, there is infrequent occurrence of perchlorate at 18 µg/L, 56 µg/L, or 90 µg/L. Therefore, the EPA did not evaluate alternative MCL values greater than the corresponding MCLG values. The purpose for evaluating alternative MCL values is to determine whether there is an MCL at which benefits justify the costs of setting an MCL. Given infrequent occurrence, the majority of the costs associated with establishing an NPDWR for perchlorate are for administrative and initial monitoring activities (see section XI.B), which will not be significantly affected by MCL values greater than corresponding MCLG values.

When proposing an MCL, the EPA must publish, and seek public comment on, the health risk reduction and cost analyses (HRRCA) of each alternative MCL considered (SDWA Section 1412(b)(3)(C)(i)), including: the quantifiable and nonquantifiable health risk reduction benefits attributable to MCL compliance; the quantifiable and nonquantifiable health risk reduction benefits of reduced exposure to co-occurring contaminants attributable to MCL compliance; the quantifiable and nonquantifiable costs of MCL compliance; the incremental costs and benefits of each alternative MCL; the effects of the contaminant on the general population and sensitive subpopulations likely to be at greater risk of exposure; any adverse health risks posed by compliance; and other factors such as data quality and uncertainty. The EPA provides this information in section XII. The EPA must base its action on the best available, peer-reviewed science and supporting studies, taking into consideration the quality of the information and the uncertainties in the benefit-cost analysis (SDWA Section 1412(b)(3)). The following sections, as well as the health effects discussion in section III document the science and studies that the EPA relied upon to develop estimates of benefits and costs and understand the impact of uncertainty on the Agency's analysis.

VI. Occurrence

The UCMR 1 is the primary source of occurrence data the EPA relied on to estimate the number of water systems (and associated population) expected to be exposed at levels of perchlorate which could potentially exceed the proposed and alternative MCL levels. Since UCMR 1 data was first used to inform the Agency actions on the 2008 preliminary regulatory determination and the 2011 final regulatory determination, the Agency has modified its analysis of the UCMR 1 data set in response to concerns raised by stakeholders regarding the data quality and to represent current conditions at some States that have enacted perchlorate regulations since the UCMR 1 data was collected. Despite these updates, the EPA continues to rely on the UCMR 1 data because they are the best available data collected in accordance with accepted methods from a census of the large water systems (serving more than 10,000 people) and a statistically representative sample of small water systems that provides the best available, national assessment of perchlorate occurrence in drinking water.

In 1999, the EPA developed the first round of the UCMR program in accordance with SDWA requirements to provide national occurrence information on unregulated contaminants

(USEPA, 1999, 2000b). The UCMR 1 required sampling from systems in all 50 States, the District of Columbia, four U.S. territories, and tribal lands in five EPA Regions including:

- all 3,097 large (serving more than 10,000 people) CWSs and NTNCWSs, which analyzed either four quarterly samples collected at 3-month intervals (surface water sources), or two samples collected 5 to 7 months apart (ground water sources); and
- a statistically representative selection of 800 small CWSs and NTNCWSs, which analyzed either four quarterly samples collected at 3-month intervals (surface water sources) or two samples collected 5 to 7 months apart (ground water sources).

Water systems submitted UCMR 1 sampling results to the EPA from 2001 until 2005. Water systems were required to analyze samples for 26 contaminants including perchlorate. The EPA established a minimum reporting level of 4 μg/L for perchlorate in the UCMR.

The EPA conducted a data quality review of the UCMR 1 data submitted by systems prior to analyzing the occurrence data for the 2011 perchlorate regulatory determination. The UCMR 1 dataset used by the EPA included 34,331 samples with 637 measurements of perchlorate above the minimum reporting level from 3,865 systems.

In September of 2012, the EPA received a "Request for Correction" letter from the United States Chamber of Commerce regarding information and data (i.e., the occurrence of perchlorate in drinking water) used by the EPA in its 2011 determination to regulate perchlorate. The U.S. Chamber of Commerce letter stated that the EPA relied upon: 1) data that did not comply with data quality guidelines and 2) data that was not representative of current conditions.

In response[12] to the U.S. Chamber of Commerce, the EPA conducted a detailed assessment of the source water sample detections and determined that it was most appropriate to exclude the source water sample detections from the UCMR 1 perchlorate data set when those samples had appropriate follow-up entry point samples that were included in the UCMR 1 perchlorate data set. In contrast, any source water sample perchlorate detections for which no follow-up entry point sampling was conducted by PWSs were retained in the UCMR 1 perchlorate data set. As a result of the assessment, the EPA removed 199 source water samples (97 detections) that could be paired with a second follow-up sample located at the entry point to the distribution system. Following this convention, the resulting UCMR 1 data set contains 34,132 perchlorate samples from 3,865 systems with a total of 540 detections from 149 PWSs.

Table VI-1 shows sample distribution by system size category and measurement status. It also shows the number of entry points and systems where perchlorate measurements were reported. The entry point estimates differ from the system estimates because many water systems have more than one entry point. For example, a ground water system with two wells that has separate connections to the distribution system has two entry points.

In response to the U.S. Chamber of Commerce request, the EPA has also reassessed the UCMR 1 data in light of the adoption of regulatory limits in two states. Massachusetts promulgated a drinking water standard for perchlorate of 2 μg/L in 2006 [ADDIN ZOTERO_ITEM CSL_CITATION

[12] See the EPA response letter at https://www.epa.gov/sites/production/files/2017-08/documents/12004-response_0.pdf

{"citationID":"8DPpSrv3","properties":{"formattedCitation":"(MassDEP, 2006)","plainCitation":"(MassDEP, 2006)","noteIndex":0},"citationItems":[{"id":151,"uris":["http://zotero.org/groups/945096/items/9893MBZH"],"uri":["http://zotero.org/groups/945096/items/9893MBZH"],"itemData":{"id":151,"type":"personal_communication","title":"Letter to Public Water Suppliers concerning new perchlorate regulations","URL":"https://www.mass.gov/lists/perchlorate-background-information-and-standards#perchlorate---final-standards-","author":[{"literal":"MassDEP"}],"issued":{"date-parts":[["2006"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], and California promulgated a drinking water standard of 6 μg/L in 2007 [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"cfr6HNhg","properties":{"formattedCitation":"(California Department of Public Health, 2007)","plainCitation":"(California Department of Public Health, 2007)","noteIndex":0},"citationItems":[{"id":150,"uris":["http://zotero.org/groups/945096/items/RA45NKLQ"],"uri":["http://zotero.org/groups/945096/items/RA45NKLQ"],"itemData":{"id":150,"type":"personal_communication","title":"State Adoption of a Perchlorate Standard","URL":"https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/perchlorate/AdoptionMemotoWaterSystems-10-2007.pdf","author":[{"literal":"California Department of Public Health"}],"issued":{"date-parts":[["2007"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Systems in these states are now required to keep perchlorate levels in drinking water below their state limits, which are lower than the proposed MCL and alternative MCLs. Therefore, the UCMR 1 sampling results from systems in these states do not reflect the current occurrence and exposure conditions. For the purpose of estimating the costs and benefits of the proposed rule, the EPA assumed that no additional monitoring and treatment costs would be incurred by the systems in the States of California and Massachusetts. Systems in California account for some of the perchlorate measurements reported below. The notes in the tables below indicate whether results include or exclude systems in California and Massachusetts.

To update the occurrence data for systems sampled during UCMR 1 from the States of California and Massachusetts, the EPA identified all systems and corresponding entry points which had reported perchlorate detections in UCMR 1. Once the systems and entry points with detections were appropriately identified, the EPA then used a combination of available data from Consumer Confidence Reports (CCRs) and perchlorate compliance monitoring data from California (https://sdwis.waterboards.ca.gov/PDWW/) and Massachusetts (https://www.mass.gov/service-details/public-water-supplier-document-search) to match current compliance monitoring data (where available) to the corresponding water systems and entry points sampled during UCMR 1.

Out of the 540 detections previously described the EPA updated data for 321 detections (320 from California systems and 1 from a Massachusetts system). The convention used by the EPA to accomplish the substitution of data was to match entry points with compliance data for active entry points based on most recently reported compliance monitoring data, if more than one data point was reported for an entry point, the assigned value is an average of the annual monitoring results at the entry point. In cases were the EPA could not find updated entry point data, then the original data from UCMR 1 for such entry point was kept.

Table VI-1. UCMR 1 Data Summary Statistics

Item	Small System Sample	Large System Census	Sum
Total samples	3,295	30,837	34,132
Sample measurements ≥ 4 µg/L	15	525	540
Sample measurements > 18 µg/L	1	16	17
Sample measurements > 56 µg/L	0	2	2
Sample measurements > 90 µg/L	0	1	1
Total entry points	1,454	13,482	14,936
Entry points at which measurements ≥ 4 µg/L	8	328	336
Entry points at which measurements > 18 µg/L	1	16	17
Entry points at which measurements > 56 µg/L	0	2	2
Entry points at which measurements > 90 µg/L	0	1	1
Total systems	797	3,068	3,865
Systems at which measurements ≥ 4 µg/L	8	141	149
Systems at which measurements > 18 µg/L	1	14	15
Systems at which measurements > 56 µg/L	0	2	2
Systems at which measurements > 90 µg/L	0	1	1

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"UAoGFPZv","properties":{"formattedCitation":"(USEPA, 2018)","plainCitation":"(USEPA, 2018)","noteIndex":0},"citationItems":[{"id":969,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":969,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The total row counts and counts of measurements ≥ 4 µg/L identify all instances where perchlorate was detected at or above the minimum reporting level, including water systems in California and Massachusetts, which account for 537 systems in total and 51 systems at which measurements ≥4 µg/L. The instances where perchlorate measurements equal or exceed either 18 µg/L, 56µg/L, or 90 µg/L exclude results from California and Massachusetts because water systems in these States must meet limits below 18 µg/L. The small system counts reflect sample results that have not been extrapolated to small systems nationwide.

Table VI-2 shows the service populations that correspond with the occurrence summary in Table VI-1. The entry point population estimates reflect the assumption that system population is uniformly distributed across entry points; e.g., the entry point population for a system with two entry points is one-half the total system population.

Table VI-2. UCMR1 Data Service Population Summary Statistics

Item	Small System Sample	Large System Census	Sum
Total entry point population	2,760,570	222,853,101	225,613,671
Population served by entry points at which measurements ≥ 4 μg/L	9,484	4,281,937	4,291,420
Population served by entry points at which measurements > 18 μg/L	2,155	618,406	620,560
Population served by entry points at which measurements > 56 μg/L	0	32,432	32,432
Population served by entry points at which measurements > 90 μg/L	0	25,972	25,972
Total system population	2,760,570	222,853,101	225,613,671
Population served by systems at which measurements ≥ 4 μg/L	13,483	16,159,082	16,172,565
Population served by systems at which measurements >18 μg/L	4,309	696,871	701,180
Population served by systems at which measurements > 56 μg/L	0	64,733	64,733
Population served by systems at which measurements > 90 μg/L	0	25,972	25,972

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ChxDKgDr","properties":{"formattedCitation":"(USEPA, 2018)","plainCitation":"(USEPA, 2018)","noteIndex":0},"citationItems":[{"id":969,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":969,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The populations for entry points/systems with measurements ≥ 4 μg/L identify all instances where perchlorate was detected at or above the minimum reporting level, including water systems in California and Massachusetts, which account for 39.6 million of the 225.6 million total population in UCMR 1, and 1.9 million of the 4.3 million population served by entry points at which measurements ≥4 μg/L. The instances where perchlorate measurements equal or exceed either 18 μg/L, 56μg/L, or 90 μg/L exclude results from California and Massachusetts because water systems in these States must meet limits below 18 μg/L. The small system counts reflect sample results that have not been extrapolated to small systems nationwide.

As shown in the tables, 149 systems serving 16.2 million people had measured levels of perchlorate greater than the minimum reporting level. However, many of these systems have several entry points with no measured levels of perchlorate greater than the minimum reporting level; at the entry point level, the exposed population is approximately 4.3 million people served by 336 entry points. Because the uniform population distribution assumption may over or underestimate the service population of any particular entry point, the entry point estimates are uncertain. The system population estimates serve as upper bounds on exposure.

The EPA used entry point maximum measurements to estimate potential baseline occurrence and exposure at levels that exceed the proposed MCL and alternative MCLs. The maximum measurements indicate perchlorate levels that occurred in at least one quarterly sample among surface water systems and at least one semi-annual sample among ground water systems.

Table VI-3 through Table VI-5 show the occurrence and exposure estimates based on the 56 µg/L, 18 µg/L MCL, and 90 µg/L values, respectively. Each table provides estimates of the entry points at which the maximum perchlorate concentrations exceed the MCL value. The tables also report the system-level information for these entry points.

Table VI-3: Estimated Perchlorate Occurrence and Exposure: Entry Point Max Exceeds 56 µg/L

Affected Entity	Small Systems	Large Systems	Total Systems
Entry points	0	2	2
Population served	0	32,432	32,432
Water systems	0	2	2
Population served	0	64,733	64,733

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"adhRbcXq","properties":{"formattedCitation":"(USEPA, 2018c)","plainCitation":"(USEPA, 2018c)","noteIndex":0},"citationItems":[{"id":155,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":155,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Table VI-4: Estimated Perchlorate Occurrence and Exposure: Entry Point Max Exceeds 18 μg/L

Affected Entity	Small Systems[1]	Large Systems	Total Systems
Entry points	1	16	17
Population served	2,155	618,406	620,560
Water systems	1	14	15
Population served	4,309	696,871	701,180

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"z4saRTHP","properties":{"formattedCitation":"(USEPA, 2018c)","plainCitation":"(USEPA, 2018c)","noteIndex":0},"citationItems":[{"id":155,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":155,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

1. The values shown in the table are estimates based on the UCMR 1 data. The EPA also applied the statistical sampling weights to the results to extrapolate results to national results. The entry point at which a measurement exceeds 18 μg/L is one of 20 in its sample stratum; no other sample in the stratum had a measurement of perchlorate greater than the minimum reporting level. The entry point population of 2,155 represents 5.31% of the total population served by the six UCMR 1 systems in the stratum (40,574). Currently, the stratum population of 774,780 accounts for 1.32% of the 58.7 million national population served by small systems. Thus, the UCMR 1 results indicate that 0.07% (5.31% x 1.32%) of small system customers (approximately 41,100) may be exposed to perchlorate greater than 18 μg/L.

Table VI-5: Estimated Perchlorate Occurrence and Exposure: Entry Point Max Exceeds 90 µg/L

Affected Entity	Small Systems[1]	Large Systems	Total Systems
Entry points	0	1	1
Population served	0	25,972	25,972
Water systems	0	1	1
Population served	0	25,972	25,972

Source: [ADDIN ZOTERO_ITEM CSL_CITATION
{"citationID":"z4saRTHP","properties":{"formattedCitation":"(USEPA, 2018c)","plainCitation":"(USEPA, 2018c)","noteIndex":0},"citationItems":[{"id":155,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":155,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

In summary, the perchlorate occurrence information suggests that at an MCL of 56 µg/L, two systems (0.004% of all water systems in the U.S.) would exceed the regulatory threshold. One of these two systems would exceed the alternative MCL of 90 µg/L. In addition, at an MCL of 18 µg/L, there would be 15 systems (0.03% of all water systems in the U.S.) that would exceed the regulatory threshold.

VII. Analytical Methods

The SDWA directs the EPA to set a contaminant's MCL as close to its MCLG as is ''feasible'', the definition of which includes an evaluation of the feasibility of performing chemical analysis of the contaminant at standard drinking water laboratories. Specifically, the SDWA directs the EPA to determine that it is economically and technologically feasible to ascertain the level of the contaminant being regulated in water in public water systems (Section 1401(1)(C)(i)). NPDWRs are also to contain ''criteria and procedures to assure a supply of drinking water which dependably complies with such [MCLs]; including accepted methods for quality control and testing procedures to insure compliance with such levels.'' (Section 1401(1)(D)).

To comply with these requirements, the EPA considers method performance under relevant laboratory conditions, their likely prevalence in certified drinking water laboratories, and the associated analytical costs. The EPA has developed five analytical methods for the identification and quantification of perchlorate in drinking water that meet these criteria. The proposed EPA methods for perchlorate are: 314.0, 314.1, 314.2, 331.0, and 332.0. A detailed description of these methods is presented in the Perchlorate Occurrence and Monitoring Report (USEPA, 2019b).

The EPA Methods 314.0, 314.1, 314.2, 331.0, and 332.0 underwent the EPA's analytical method development and validation processes. The validation process includes a protocol for modifications to any existing EPA-approved analytical methods and a protocol for new determinative techniques. Both validation protocols are rigorous and consider many technical aspects of analytical method performance, including: detection limits; instrument calibration; precision and analyte recovery; analyte retention times; evaluation of blanks; development of Quality Control acceptance criteria; analysis of field samples; and other technical aspects of sample analysis and data reporting. All of the proposed EPA analytical methods provide performance data to demonstrate their capability to reliably and consistently measure perchlorate in drinking water at the proposed and alternate MCLs.

VIII. Monitoring and Compliance Requirements

A. What are the Proposed Monitoring Requirements?

The EPA is proposing to require CWS and NTNCWSs to monitor for perchlorate in accordance with the standardized monitoring framework set out in 40 CFR 141 Subpart C (Standardized Monitoring Framework). Public water systems must sample entry points to the distribution system consistent with requirements in 40 CFR 141.23(a).

Under the Standardized Monitoring Framework, the monitoring frequency for a public water system is dependent on previous monitoring results and whether a monitoring waiver has been granted. The EPA is proposing that consistent with the standardized monitoring framework water systems would be initially required to monitor quarterly for perchlorate. The EPA is also proposing that based upon the monitoring results States would be able to reduce the monitoring frequency to annually, once every three years or once every nine years if the State concludes that the system is reliably and consistently below the MCL. If a water system exceeds the perchlorate MCL, the system is in violation and triggered into quarterly monitoring for that sampling point in the next quarter after the violation occurred (40 CFR 141.23(c)(7)). The state may allow the system to return to the reduced monitoring frequency when the state determines that the system is reliably and consistently below the MCL. However, the state cannot make a determination that the system is reliably and consistently below the MCL until a minimum of 2 consecutive ground water or 4 consecutive surface water samples below the MCL have been collected (40 CFR

141.23(c)(8)). All systems must comply with the sampling requirements, unless a waiver has been granted in writing by the state (40 CFR 141.23(c)(6)).

B. Can States Grant Monitoring Waivers?

Under this proposal, water systems may apply to the state, and states may grant, a 9-year monitoring waiver for perchlorate if the conditions described in 40 CFR 141.23(c)(3)-(6) are met. A state may grant a waiver for surface water systems after three rounds of annual monitoring with results less than the MCL and for groundwater systems after conducting three rounds of monitoring with results less than the MCL. One sample must be collected during the nine-year compliance cycle that the waiver is effective, and the waiver must be renewed every nine years.

C. How are System MCL Violations Determined?

Under this proposal, violations of the perchlorate MCL would be determined in a manner consistent with 40 CFR 141.23(i)(3). Compliance with the perchlorate MCL would be determined based on one sample if the level is below the MCL. If the level of perchlorate exceeds the MCL at any entry point in the initial sample, a confirmation sample is required within two weeks of the system's receipt of notification of the analytical result of the first sample, in accordance with 141.23(f)(1). Compliance shall be determined based on the average of the initial and confirmation samples.

D. When Must Systems Complete Initial Monitoring?

Pursuant to Section 1412(b)(10), this rule would be effective three years after promulgation. To satisfy initial monitoring requirements, CWS serving populations greater than

10,000 persons must collect 4 quarterly samples for perchlorate during the second compliance period of the fourth compliance cycle (January 1, 2023– December 31, 2025) of the Standardized Monitoring Framework. NTNCWS and CWSs serving 10,000 persons or less must collect 4 quarterly samples during the third compliance period of the fourth compliance cycle (January 1, 2026 – December 31, 2028) of the Standardized Monitoring Framework.

E. Can Systems use Grandfathered Data to Satisfy the Initial Monitoring Requirements?

As proposed today, systems would be allowed to use grandfathered perchlorate data collected after January 1, 2020, to satisfy the initial monitoring requirements. To satisfy initial perchlorate monitoring requirements, a system with appropriate historical monitoring data for each entry point to the distribution system could use the monitoring data from the compliance monitoring period between January 1, 2020, and December 31, 2022, for CWSs serving greater than 10,000 persons and between January 1, 2023, and December 31, 2025, for NTNCWs and for CWSs serving 10,000 or fewer persons.

IX. Safe Drinking Water Act Right to Know Requirements

A. What are the Consumer Confidence Report Requirements?

A community water system must prepare and deliver to its customers an annual Consumer Confidence Report (CCR) in accordance with requirements in 40 CFR 141 Subpart O. A CCR provides customers with information about their local drinking water quality as well as information regarding the water system compliance with drinking water regulations. Under this proposal CWSs would be required to report perchlorate information in their CCR.

B. What are the Public Notification Requirements?

All public water systems must give the public notice for all violations of NPDWRs and for other situations. Under this proposal, violations of the perchlorate MCL would be designated as Tier 1 and as such, public water systems would be required to comply with 40 CFR 141.202. As described in Section III of this proposal, fetuses of first trimester pregnant women with low iodine are the most sensitive subpopulation, therefore, per 40 CFR 141.202(b)(1), notification of an MCL violation should be provided as soon as practicable but no later than 24 hours after the system learns of the violation under this proposal.

X. Treatment Technologies

Systems that exceed the perchlorate MCL will need to adopt new treatment or another strategy to reduce perchlorate to a level that meets the MCL. When the EPA establishes an MCL for a drinking water contaminant, Section 1412(b)(4)(E) of the SDWA requires that the Agency "list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting [the MCL]," which are referred to as best available technologies (BAT). These BATs are used by states to establish conditions for source water variances under Section 1415(a). Furthermore, Section 1412(b)(4)(E)(ii) requires that the Agency identify small system compliance technologies (SSCT), which are affordable treatment technologies, or other means that can achieve compliance with the MCL (or treatment technique, where applicable). The lack of an affordable SSCT for a contaminant triggers certain additional procedures which can result in states issuing small system variances under Section 1412(e) of the SDWA.

The Agency solicits public comment on the choice of available treatment technologies discussed in this section.

A. What are the Best Available Technologies?

The Agency identifies the best available technologies (BAT) as those meeting the following criteria: (1) the capability of a high removal efficiency; (2) a history of full-scale operation; (3) general geographic applicability; (4) reasonable cost based on large and metropolitan water systems; (5) reasonable service life; (6) compatibility with other water treatment processes; and (7) the ability to bring all of the water in a system into compliance. The Agency is proposing the following technologies as BAT for removal of perchlorate from drinking water based its review of the treatment and cost literature (USEPA, 2018a):

- ion exchange;
- biological treatment; and
- centralized reverse osmosis.

There are also non-treatment options that might be used for compliance in lieu of installing and operating treatment technologies. These include blending existing water sources, replacing a perchlorate-contaminated source of drinking water with a new source (e.g., a new well), and purchasing compliant water from another system. Below are brief descriptions of each proposed BAT.

Ion Exchange.

Ion exchange is a physical and chemical separation process that can achieve high perchlorate removal rates. Feed water passes through a vessel containing a bed of resin made of synthetic beads or gel. As feed water moves through the resin, an ionic contaminant such as perchlorate exchanges for an ion (typically chloride) on the resin. Demonstrated removal

efficiencies for perchlorate are typically in the high 90 percent range and can achieve concentrations less than 4 μg/L in treated water [ADDIN ZOTERO_ITEM CSL_CITATION
{"citationID":"s9dVZckb","properties":{"formattedCitation":"(Drago & Leserman, 2011;
Membrane Technology, 2006; Siemens Water Technologies, 2009; The Interstate Technology &
Regulatory Council (ITRC) Team, 2008)","plainCitation":"(Drago & Leserman, 2011;
Membrane Technology, 2006; Siemens Water Technologies, 2009; The Interstate Technology &
Regulatory Council (ITRC) Team,
2008)","noteIndex":0},"citationItems":[{"id":1048,"uris":["http://zotero.org/groups/945096/item
s/KIPNEQUM"],"uri":["http://zotero.org/groups/945096/items/KIPNEQUM"],"itemData":{"id":
1048,"type":"paper-conference","title":"Castaic Lake Water Agency Operating Experience with
Lead-Lag Anion Exchange for Perchlorate Removal","container-title":"Proceedings of the
American Water Works Association Water Quality Technology Conference","event":"Water
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cle","title":"News: Ion=Exchange System Removes Perchlorate","publisher":"Membrane
Technology","author":[{"literal":"Membrane Technology"}],"issued":{"date-
parts":[["2006",4]]}}},{"id":1125,"uris":["http://zotero.org/groups/945096/items/6WYYWFY2"]
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port","title":"Case Study: Municipality in the State of Massachusetts","author":[{"literal":"Siemens Water Technologies"}],"issued":{"date-parts":[["2009"]]}}},{"id":1118,"uris":["http://zotero.org/groups/945096/items/5PV8GPIA"],"uri":["http://zotero.org/groups/945096/items/5PV8GPIA"],"itemData":{"id":1118,"type":"article","title":"Technical/Regulatory Guidance: Remediation Technologies for Perchlorate Contamination in Water and Soil","URL":"http://www.eosremediation.com/download/Perchlorate/ITRC%20PERC-2.pdf","author":[{"literal":"The Interstate Technology & Regulatory Council (ITRC) Team"}],"issued":{"date-parts":[["2008",3]]},"accessed":{"date-parts":[["2018",10,13]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The operation continues until enough of the resin's available ion exchange sites have ions from the feed water and the resin no longer effectively removes the target contaminant, i.e., the contaminant "breaks through" the treatment process. At this point, the resin must be disposed and replaced or regenerated. The length of time until resin must be replaced or regenerated is known as bed life and is a critical factor in the cost effectiveness of ion exchange as a treatment technology. One measurement of bed life is the volume of water that can be treated before breakthrough – called bed volumes – the number of times the resin bed can be filled before breakthrough. Several factors affect bed life, including the presence of competing ions such as nitrate and the type of resin used. Resin types tested for perchlorate removal include strong-base polyacrylic, strong-base polystyrenic (including nitrate-selective), weak-base polyacrylic, weak-base polystyrenic, and perchlorate-selective. Based on studies of the effect of competing ions on performance, perchlorate-selective resins can achieve bed lives ranging from 105,000 to 170,000 bed volumes [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"cxQjBTo8","properties":{"formattedCitation":"(Blute, Seidel, McGuire, Qin, & Byerrum, 2006; Russell, Qin, Blute, McGuire, & Williams, 2008; Wu & Blute, 2010)","plainCitation":"(Blute, Seidel, McGuire, Qin, & Byerrum, 2006; Russell, Qin, Blute, McGuire, & Williams, 2008; Wu & Blute, 2010)","noteIndex":0},"citationItems":[{"id":1076,"uris":["http://zotero.org/groups/945096/items/8Z7K9ZUJ"],"uri":["http://zotero.org/groups/945096/items/8Z7K9ZUJ"],"itemData":{"id":1076,"type":"speech","title":"Bench and Pilot Testing of High Capacity, Single-Pass Ion Exchange Resins for Perchlorate Removal","publisher-place":"San Antonio, TX","event":"2006 AWWA Annual Conference & Exposition","event-place":"San Antonio, TX","author":[{"family":"Blute","given":"N.K."},{"family":"Seidel","given":"C.J."},{"family":"McGuire","given":"M.J."},{"family":"Qin","given":"D."},{"family":"Byerrum","given":"J."}],"issued":{"date-parts":[["2006",6]]}}},{"id":1132,"uris":["http://zotero.org/groups/945096/items/NLAFHBV2"],"uri":["http://zotero.org/groups/945096/items/NLAFHBV2"],"itemData":{"id":1132,"type":"speech","title":"Pilot Testing of Single Pass Perchlorate-Selective Ion Exchange Resins at Three Utilities in the Main San Gabriel Basin","publisher-place":"Cincinnati, OH","event":"AWWA Water Quality Technology Conference & Exposition","event-place":"Cincinnati, OH","author":[{"family":"Russell","given":"C.G."},{"family":"Qin","given":"G."},{"family":"Blute","given":"N.K."},{"family":"McGuire","given":"M.J."},{"family":"Williams","given":"C."}

],"issued":{"date-parts":[["2008",11]]}}},{"id":1094,"uris":["http://zotero.org/groups/945096/items/2QPEXW23"],"uri":["http://zotero.org/groups/945096/items/2QPEXW23"],"itemData":{"id":1094,"type":"speech","title":"Perchlorate Removal Using Single-Pass Ion Exchange Resin - Pilot Testing Purolite A532E at the San Gabriel B6 Plant","publisher-place":"Hollywood, CA","event":"2010 California-Nevada AWWA Spring Conference","event-place":"Hollywood, CA","author":[{"family":"Wu","given":"X."},{"family":"Blute","given":"N.K."}],"issued":{"date-parts":[["2010",3,31]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Perchlorate-selective resin cannot be easily regenerated for reuse; the exhausted resin must be disposed (i.e., operated on a 'throw-away' basis). This mode of operation, however, avoids the production of liquid residuals in the form of spent regenerant. Therefore, in combination with the long bed life, single-use perchlorate-selective ion exchange can be a cost-effective treatment option in spite of the need to dispose of the perchlorate-contaminated resin. Build-up of arsenic or uranium on the resin may affect waste disposal options, although studies of perchlorate-selective resins show that arsenic concentrations remain below regulatory limits for hazardous waste disposal and uranium concentrations generally remain below those that require special handling as radioactive waste [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"I0SaZZiL","properties":{"formattedCitation":"(Blute et al., 2006; Russell et al., 2008; Wu & Blute, 2010)","plainCitation":"(Blute et al., 2006; Russell et al., 2008; Wu & Blute, 2010)","noteIndex":0},"citationItems":[{"id":1076,"uris":["http://zotero.org/groups/945096/item s/8Z7K9ZUJ"],"uri":["http://zotero.org/groups/945096/items/8Z7K9ZUJ"],"itemData":{"id":1076,"type":"speech","title":"Bench and Pilot Testing of High Capacity, Single-Pass Ion Exchange Resins for Perchlorate Removal","publisher-place":"San Antonio, TX","event":"2006 AWWA Annual Conference & Exposition","event-place":"San Antonio, TX","author":[{"family":"Blute","given":"N.K."},{"family":"Seidel","given":"C.J."},{"family":"McGuire","given":"M.J."},{"family":"Qin","given":"D."},{"family":"Byerrum","given":"J."}],"issued":{"date-parts":[["2006",6]]}}},{"id":1132,"uris":["http://zotero.org/groups/945096/items/NLAFHBV2"],"uri":["http://zotero.org/groups/945096/items/NLAFHBV2"],"itemData":{"id":1132,"type":"speech","title":"Pilot Testing of Single Pass Perchlorate-Selective Ion Exchange Resins at Three Utilities in the Main San Gabriel Basin","publisher-place":"Cincinnati, OH","event":"AWWA Water Quality Technology Conference & Exposition","event-place":"Cincinnati, OH","author":[{"family":"Russell","given":"C.G."},{"family":"Qin","given":"G."},{"family":"Blute","given":"N.K."},{"family":"McGuire","given":"M.J."},{"family":"Williams","given":"C."}],"issued":{"date-parts":[["2008",11]]}}},{"id":1094,"uris":["http://zotero.org/groups/945096/items/2QPEXW23"],"uri":["http://zotero.org/groups/945096/items/2QPEXW23"],"itemData":{"id":1094,"type":"speech","title":"Perchlorate Removal Using Single-Pass Ion Exchange Resin - Pilot Testing Purolite A532E at the San Gabriel B6 Plant","publisher-place":"Hollywood, CA","event":"2010 California-Nevada AWWA Spring Conference","event-place":"Hollywood, CA","author":[{"family":"Wu","given":"X."},{"family":"Blute","given":"N.K."}],"issued":{"dat e-parts":[["2010",3,31]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Ion exchange can increase the corrosivity of treated water [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"dcLyBjzj","properties":{"formattedCitation":"(Berlien, 2003; Betts, 1998; USEPA, 2005b)","plainCitation":"(Berlien, 2003; Betts, 1998; USEPA, 2005b)","noteIndex":0},"citationItems":[{"id":1079,"uris":["http://zotero.org/groups/945096/items/8PB22K95"],"uri":["http://zotero.org/groups/945096/items/8PB22K95"],"itemData":{"id":1079,"type":"report","title":"La Puente Valley County Water District's Experience with ISEP","collection-title":"Presentation of Carollo Engineers, Inc. and Association of California Water Agencies","author":[{"family":"Berlien","given":"M.J."}],"issued":{"date-parts":[["2003",4]]}}},{"id":1078,"uris":["http://zotero.org/groups/945096/items/BNWD5VQP"],"uri":["http://zotero.org/groups/945096/items/BNWD5VQP"],"itemData":{"id":1078,"type":"article-journal","title":"Rotation ion-exchange system removes perchlorate","page":"454A-455A","volume":"32","journalAbbreviation":"Environ. Sci. Technol.","author":[{"family":"Betts","given":"K.S."}],"issued":{"date-parts":[["1998"]]}}},{"id":1208,"uris":["http://zotero.org/groups/945096/items/EWAQ4GEK"],"uri":["http://zotero.org/groups/945096/items/EWAQ4GEK"],"itemData":{"id":1208,"type":"article","title":"Perchlorate Treatment Technology Update: Federal Facilities Forum Issue Paper","publisher":"Office of Solid Waste and Emergency Response. EPA 542-R-05-015","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2005",5]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] because of the addition of chloride ions and/or removal of carbonates and bicarbonates. Such instances can be addressed by adding or adjusting corrosion control.

Biological Treatment.

Biological treatment uses bacteria to reduce perchlorate to chlorate, chlorite, chloride, and oxygen. Biological treatment can destroy the perchlorate ion, eliminating the need for management of perchlorate-bearing waste streams. Removal effectiveness exceeds 90 percent for bench-scale tests and full-scale treatment plant studies [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"CnYkqct9","properties":{"formattedCitation":"(Kotlarz, Upadhyaya, Togna, & Raskin, 2016; Upadhyaya, Kotlarz, Togna, & Raskin, 2015; U.S. Department of Defense (U.S. DoD), 2008, 2009; T. D. Webster & Crowley, 2010, 2016; T. D. Webster & Litchfield, 2017)","plainCitation":"(Kotlarz, Upadhyaya, Togna, & Raskin, 2016; Upadhyaya, Kotlarz, Togna, & Raskin, 2015; U.S. Department of Defense (U.S. DoD), 2008, 2009; T. D. Webster & Crowley, 2010, 2016; T. D. Webster & Litchfield, 2017)","noteIndex":0},"citationItems":[{"id":1019,"uris":["http://zotero.org/groups/945096/items/E5WRR4HD"],"uri":["http://zotero.org/groups/945096/items/E5WRR4HD"],"itemData":{"id":1019,"type":"article-journal","title":"Evaluation of electron donors for biological perchlorate removal highlights the importance of diverse perchlorate-reducing populations","container-title":"Environmental Science: Water Research & Technology","page":"1049-1063","volume":"2","author":[{"family":"Kotlarz","given":"N."},{"family":"Upadhyaya","given":"G."},{"family":"Togna","given":"P."},{"family":"Raskin","given":"L."}],"issued":{"date-parts":[["2016"]]}}},{"id":1106,"uris":["http://zotero.org/groups/945096/items/KLWCLIE4"],"uri":["http://zotero.org/groups/945096/items/KLWCLIE4"],"itemData":{"id":1106,"type":"article-journal","title":"Carbohydrate-Based Electron Donor for Biological Nitrate and Perchlorate Removal From Drinking Water","container-title":"Journal - American Water Works Association","page":"E674-E684","volume":"107","issue":"12","source":"Wiley Online Library","abstract":"This study evaluated the feasibility of replacing acetic acid with a commercial carbohydrate-based electron donor (CBED) for removal of nitrate and perchlorate (ClO4–) from drinking water. Bench-scale biologically active carbon fixed-bed and fluidized-bed reactors (FXBR and FLBR, respectively), with an initial empty bed contact time (EBCT) of 42.8 min, were fed simulated groundwater containing 15 mg/L nitrate as nitrogen and 200 μg/L ClO4–. EBCT in the FLBR after final expansion was 80.5 min. During the first 100 days using acetic acid at 125 mg/L chemical oxygen demand (COD), complete nitrate removal was achieved in both systems, whereas perchlorate in the FXBR and FLBR effluents remained below 3 and 6 μg/L ClO4–, respectively. For comparable removals, influent COD requirement was higher with the CBED. Biomass yields with acetic acid and the CBED were 0.54–0.58 and 0.59–0.74 mg CODbiomass/mg CODsubstrate, respectively. The higher yield with the CBED resulted in more frequent maintenance requirements.","DOI":"10.5942/jawwa.2015.107.0143","ISSN":"1551-8833","language":"en","author":[{"family":"Upadhyaya","given":"Giridhar"},{"family":"Kotlarz","given":"Nadine"},{"family":"Togna","given":"Paul"},{"family":"Raskin","given":"Lutgarde"}],"issued":{"date-parts":[["2015",12,1]]}}},{"id":1110,"uris":["http://zotero.org/groups/945096/items/VE5JI4GQ"

],"uri":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"itemData":{"id":1110,"type":"repo rt","title":"Perchlorate Removal, Destruction, and Field Monitoring Demonstration (Drinking Water - Pilot Scale)","collection-title":"ESTCP Cost and Performance Report (ER-0312)","author":[{"literal":"U.S. Department of Defense (U.S. DoD)"}],"issued":{"date-parts":[["2008"]]}}},{"id":1116,"uris":["http://zotero.org/groups/945096/items/9FHLVTXY"],"uri":["http://zotero.org/groups/945096/items/9FHLVTXY"],"itemData":{"id":1116,"type":"report","title":"Demonstration of a Full-Scale Fluidized Bed Bioreactor for the Treatment of Perchlorate at Low Concentrations in Groundwater","genre":"Environmental Security Technology Certification Program (ESTCP) Final Report (ER-0543)","author":[{"family":"U.S. Department of Defense (U.S. DoD)","given":""}],"issued":{"date-parts":[["2009"]]}}},{"id":1093,"uris":["http://zotero.org/groups/945096/items/BI7SF8HW"],"uri":["http://zotero.org/groups/945096/items/BI7SF8HW"],"itemData":{"id":1093,"type":"speech","title":"Full-Scale Implementation of a Biological Fluidized Bed Drinking Water Treatment Plant for Nitrate and Perchlorate Treatment","publisher-place":"Ontario, CA","event":"2010 Water Education Foundation Water Quality and Regulatory Conference","event-place":"Ontario, CA","author":[{"family":"Webster","given":"T.D."},{"family":"Crowley","given":"T.J."}],"issued":{"date-parts":[["2010",11,3]]}}},{"id":989,"uris":["http://zotero.org/groups/945096/items/BI5LYMZP"],"uri":["http://zotero.org/groups/945096/items/BI5LYMZP"],"itemData":{"id":989,"type":"speech","title":"Biological treatment of perchlorate in groundwater.","event":"AWWA Annual Conference and

Exposition","author":[{"family":"Webster","given":"T.D."},{"family":"Crowley","given":"T.J."}],"issued":{"date-parts":[["2016",6,21]]}}},{"id":990,"uris":["http://zotero.org/groups/945096/items/64HZKA2M"],"uri":["http://zotero.org/groups/945096/items/64HZKA2M"],"itemData":{"id":990,"type":"article-journal","title":"Full-scale biological treatment of nitrate and perchlorate for potable water production","container-title":"Journal AWWA","page":"30-40","volume":"109","issue":"5","author":[{"family":"Webster","given":"T.D."},{"family":"Litchfield","given":"M.H."}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Although biological treatment is a relatively new technology for treatment of drinking water in the United States, the State of California has identified biological treatment (along with ion exchange) as one of two best available technologies for achieving compliance with its standard for perchlorate in drinking water (California Code of Regulations, Title 22, Chapter 15, Section 64447.2). The California BAT specifies a fluidized bed, although studies suggest that a fixed bed is also effective. The first full-scale fluidized bed facility using biological treatment of perchlorate to supply municipal drinking water began operation in 2016 [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"nKwIqjde","properties":{"formattedCitation":"(T. D. Webster & Crowley, 2016; T. D. Webster & Litchfield, 2017)","plainCitation":"(T. D. Webster & Crowley, 2016; T. D. Webster & Litchfield, 2017)","noteIndex":0},"citationItems":[{"id":989,"uris":["http://zotero.org/groups/945096/items/

BI5LYMZP"],"uri":["http://zotero.org/groups/945096/items/BI5LYMZP"],"itemData":{"id":989,"type":"speech","title":"Biological treatment of perchlorate in groundwater.","event":"AWWA Annual Conference and Exposition","author":[{"family":"Webster","given":"T.D."},{"family":"Crowley","given":"T.J."}],"issued":{"date-parts":[["2016",6,21]]}}},{"id":990,"uris":["http://zotero.org/groups/945096/items/64HZKA2M"],"uri":["http://zotero.org/groups/945096/items/64HZKA2M"],"itemData":{"id":990,"type":"article-journal","title":"Full-scale biological treatment of nitrate and perchlorate for potable water production","container-title":"Journal AWWA","page":"30-40","volume":"109","issue":"5","author":[{"family":"Webster","given":"T.D."},{"family":"Litchfield","given":"M.H."}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Raw water quality will affect process design, in particular, temperature affects the rate of biomass growth; at temperatures below 10 degrees Celsius, growth is inhibited and bioremediation becomes infeasible [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ISPg08cl","properties":{"formattedCitation":"(Dugan, 2010b, 2010a; Dugan et al., 2009)","plainCitation":"(Dugan, 2010b, 2010a; Dugan et al., 2009)","noteIndex":0},"citationItems":[{"id":1047,"uris":["http://zotero.org/groups/945096/items/X3WWHCXS"],"uri":["http://zotero.org/groups/945096/items/X3WWHCXS"],"itemData":{"id":1047,"type":"speech","title":"The Impact of Temperature on Biological Perchlorate Removal and Downstream Effluent Polishing","publisher-place":"U.S. Environmental Protection Agency, Office of Research and Development, National Risk Management Research Laboratory","event-place":"U.S. Environmental Protection Agency, Office of Research and Development, National Risk Management Research Laboratory","author":[{"family":"Dugan","given":"N.R."}],"issued":{"date-parts":[["2010",12,8]]}}},{"id":1046,"uris":["http://zotero.org/groups/945096/items/IIXUW45F"],"uri":["http://zotero.org/groups/945096/items/IIXUW45F"],"itemData":{"id":1046,"type":"article","title":"Supporting data for presentation: The Impact of Temperature on Biological Perchlorate Removal and Downstream Effluent Polishing","publisher":"U.S. Environmental Protection Agency, Office of Research and Development, National Risk Management Research Laboratory","author":[{"family":"Dugan","given":"N.R."}],"issued":{"date-parts":[["2010",12,8]]}}},{"id":1045,"uris":["http://zotero.org/groups/945096/items/FLVLSXCS"],"uri":["http://zotero.org/groups/945096/items/FLVLSXCS"],"itemData":{"id":1045,"type":"speech","title":"The Impact of Temperature on Anaerobic Biological Perchlorate Treatment","publisher-place":"Seattle, WA","event":"2009 AWWA Water Quality Technology Conference & Exposition","event-place":"Seattle, WA","author":[{"family":"Dugan","given":"N.R."},{"family":"Williams","given":"D.J."},{"family":"Meyer","given":"M."},{"family":"Schneider","given":"R.R."},{"family":"Speth","given":"T.F."},{"family":"Metz","given":"D.H."}],"issued":{"date-parts":[["2009"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. This factor limits the feasibility of biological treatment in areas that experience low water temperatures during winter. In addition, bacteria in bioreactors require nutrients to grow and effectively reduce perchlorate. Therefore, some source waters may require supplemental addition of nutrients such as nitrogen or phosphorus [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"NDoHjLOr","properties":{"formattedCitation":"(Harding Engineering and Environmental Services (ESE), 2001; U.S. Department of Defense (U.S. DoD), 2008a, 2009)","plainCitation":"(Harding Engineering and Environmental Services (ESE), 2001; U.S. Department of Defense (U.S. DoD), 2008a, 2009)","noteIndex":0},"citationItems":[{"id":1139,"uris":["http://zotero.org/groups/945096/items/ZPGXUZPL"],"uri":["http://zotero.org/groups/945096/items/ZPGXUZPL"],"itemData":{"id":1139,"type":"report","title":"Final: Phase 2 Treatibility Study Report, Aerojet GET E/F Treatment Facility, Sacramento, California","collection-title":"Prepared for U.S. Environmental Protection Agency Region IX and Baldwin Park Operable Unit Cooperating Respondents, San Gabriel Basin,California","author":[{"family":"Harding Engineering and Environmental Services (ESE)","given":""}],"issued":{"date-parts":[["2001"]]}}},{"id":1074,"uris":["http://zotero.org/groups/945096/items/2ZCNIFHT"],"uri":["http://zotero.org/groups/945096/items/2ZCNIFHT"],"itemData":{"id":1074,"type":"report","title":"Direct Fixed-bed Biological Perchlorate Destruction Demonstration","genre":"ESTCP Final Report (ER-0544)","author":[{"literal":"U.S. Department of Defense (U.S. DoD)"}],"issued":{"date-parts":[["2008",9,25]]}}},{"id":1081,"uris":["http://zotero.org/groups/945096/items/9FHLVTXY"],"uri":["http://zotero.org/groups/945096/items/9FHLVTXY"],"itemData":{"id":1081,"type":"

report","title":"Demonstration of a Full-Scale Fluidized Bed Bioreactor for the Treatment of Perchlorate at Low Concentrations in Groundwater","genre":"Environmental Security Technology Certification Program (ESTCP) Final Report (ER-0543)","author":[{"family":"U.S. Department of Defense (U.S. DoD)","given":""}],"issued":{"date-parts":[["2009"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Although the process does not produce perchlorate-contaminated wastes, periodic removal of excess biomass, e.g., through backwash, will be required. The backwash water is non-toxic and can be discharged to a sanitary sewer [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"f4qlOob5","properties":{"formattedCitation":"(U.S. Department of Defense (U.S. DoD), 2008, 2009)","plainCitation":"(U.S. Department of Defense (U.S. DoD), 2008, 2009)","noteIndex":0},"citationItems":[{"id":1110,"uris":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"uri":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"itemData":{"id":1110,"type":"report","title":"Perchlorate Removal, Destruction, and Field Monitoring Demonstration (Drinking Water - Pilot Scale)","collection-title":"ESTCP Cost and Performance Report (ER-0312)","author":[{"literal":"U.S. Department of Defense (U.S. DoD)"}],"issued":{"date-parts":[["2008"]]}}},{"id":1116,"uris":["http://zotero.org/groups/945096/items/9FHLVTXY"],"uri":["http://zotero.org/groups/945096/items/9FHLVTXY"],"itemData":{"id":1116,"type":"report","title":"Demonstration of a Full-Scale Fluidized Bed Bioreactor for the Treatment of Perchlorate at Low Concentrations in Groundwater","genre":"Environmental Security

Technology Certification Program (ESTCP) Final Report (ER-0543)","author":[{"family":"U.S. Department of Defense (U.S. DoD)","given":""}],"issued":{"date-parts":[["2009"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] or recycled following clarification. Typically, post-treatment of treated water also will be required because biological treatment increases soluble microbial organic products, depletes oxygen, and can add turbidity and sulfides [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ySKwU3Em","properties":{"formattedCitation":"(Dordelmann, 2009; Harding Engineering and Environmental Services (ESE), 2001; U.S. Department of Defense (U.S. DoD), 2008; T. D. Webster & Crowley, 2016; T. D. Webster & Litchfield, 2017)","plainCitation":"(Dordelmann, 2009; Harding Engineering and Environmental Services (ESE), 2001; U.S. Department of Defense (U.S. DoD), 2008; T. D. Webster & Crowley, 2016; T. D. Webster & Litchfield, 2017)","noteIndex":0},"citationItems":[{"id":1051,"uris":["http://zotero.org/groups/945096/items/Z7PC3BME"],"uri":["http://zotero.org/groups/945096/items/Z7PC3BME"],"itemData":{"id":1051,"type":"speech","title":"Full-Scale Biological Denitrification Plants in Germany, Austria and Poland","publisher-place":"Seattle, WA","event":"2009 AWWA Water Quality Technology Conference & Exposition","event-place":"Seattle, WA","author":[{"family":"Dordelmann","given":"O."}],"issued":{"date-parts":[["2009",11]]}}},{"id":1026,"uris":["http://zotero.org/groups/945096/items/ZPGXUZPL"],"uri":["http://zotero.org/groups/945096/items/ZPGXUZPL"],"itemData":{"id":1026,"type":"rep ort","title":"Final: Phase 2 Treatibility Study Report, Aerojet GET E/F Treatment Facility, Sacramento, California","collection-title":"Prepared for U.S. Environmental Protection Agency Region IX and Baldwin Park Operable Unit Cooperating Respondents, San Gabriel Basin,California","author":[{"family":"Harding Engineering and Environmental Services (ESE)","given":""}],"issued":{"date-parts":[["2001"]]}},{"id":1110,"uris":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"uri":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"itemData":{"id":1110,"type":"report","title":"Perchlorate Removal, Destruction, and Field Monitoring Demonstration (Drinking Water - Pilot Scale)","collection-title":"ESTCP Cost and Performance Report (ER-0312)","author":[{"literal":"U.S. Department of Defense (U.S. DoD)"}],"issued":{"date-parts":[["2008"]]}},{"id":989,"uris":["http://zotero.org/groups/945096/items/BI5LYMZP"],"uri":["http://zotero.org/groups/945096/items/BI5LYMZP"],"itemData":{"id":989,"type":"speech","title":"Biological treatment of perchlorate in groundwater.","event":"AWWA Annual Conference and Exposition","author":[{"family":"Webster","given":"T.D."},{"family":"Crowley","given":"T.J."}],"issued":{"date-parts":[["2016",6,21]]}},{"id":990,"uris":["http://zotero.org/groups/945096/items/64HZKA2M"],"uri":["http://zotero.org/groups/945096/items/64HZKA2M"],"itemData":{"id":990,"type":"article-journal","title":"Full-scale biological treatment of nitrate and perchlorate for potable water production","container-title":"Journal AWWA","page":"30-40","volume":"109","issue":"5","author":[{"family":"Webster","given":"T.D."},{"family":"Litch field","given":"M.H."}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The treatment process, however, can result in removal of co-occurring contaminants such as nitrate (Upadhyaya et al., 2015; Webster and Crowley, 2010; Webster and Lichfield, 2017).

Reverse Osmosis.

Reverse osmosis is a membrane filtration process that physically removes perchlorate ions from drinking water. This process separates a solute such as perchlorate ions from a solution by forcing the solvent to flow through a membrane at a pressure greater than the normal osmotic pressure. The membrane is semi-permeable, transporting different molecular species at different rates. Water and low-molecular weight solutes pass through the membrane and are removed as permeate, or filtrate. Dissolved and suspended solids are rejected by the membrane and are removed as concentrate or reject. This technique does not destroy the perchlorate ion and, therefore, creates a subsequent need for disposal or treatment of perchlorate-contaminated waste (the concentrate).

Membranes may remove ions from feed water by a sieving action (called steric exclusion), or by electrostatic repulsion of ions from the charged membrane surface. Across multiple bench- and pilot-scale studies, reverse osmosis membranes consistently achieve perchlorate removal greater than 80 percent and up to 98 percent [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"edXX3GgQ","properties":{"formattedCitation":"(Liang, Scott, Palencia, & Bruno, 1998; Nam et al., 2005; Yoon, Amy, & Yoon, 2005; Yoon, Yoon, Amy, &

Her, 2005)","plainCitation":"(Liang, Scott, Palencia, & Bruno, 1998; Nam et al., 2005; Yoon, Amy, & Yoon, 2005; Yoon, Yoon, Amy, & Her, 2005)","noteIndex":0},"citationItems":[{"id":985,"uris":["http://zotero.org/groups/945096/items/IQVVPD73"],"uri":["http://zotero.org/groups/945096/items/IQVVPD73"],"itemData":{"id":985, "type":"paper-conference","title":"Investigation of Treatment Options for Perchlorate Removal.","publisher":"La Verne, CA: Metropolitan Water District of Southern California","publisher-place":"San Diego, CA","event":"AWWA Water Quality Technology Conference","event-place":"San Diego, CA","author":[{"family":"Liang","given":"S."},{"family":"Scott","given":"K.N."},{"family":"Palencia","given":"L.S."},{"family":"Bruno","given":"J."}],"issued":{"date-parts":[["1998"]]}}},{"id":986,"uris":["http://zotero.org/groups/945096/items/YHEV76YW"],"uri":["http://zotero.org/groups/945096/items/YHEV76YW"],"itemData":{"id":986,"type":"paper-conference","title":"Perchlorate Rejection by High-Pressure Membranes and Brine Stream Treatment by Chemical and Biological Processes.","publisher-place":"Phoenix, AZ","event":"American Water Works Association Membrane Technology Conference","event-place":"Phoenix, AZ","author":[{"family":"Nam","given":"S."},{"family":"Kim","given":"S."},{"family":"Choi", "given":"H."},{"family":"Yoon","given":""},{"family":"Silverstein","given":"J."},{"family":"Amy","given":"G."}],"issued":{"date-parts":[["2005"]]}}},{"id":992,"uris":["http://zotero.org/groups/945096/items/HPHVBSWB"],"uri":["http://zotero.org/groups/945096/items/HPHVBSWB"],"itemData":{"id":992,"type":"article-journal","title":"Transport of target anions, chromate (Cr (VI)), arsenate (As (V)), and perchlorate (ClO4), through RO, NF, and UF membranes.","container-title":"Water Science and Technology","page":"327-334","volume":"51","issue":"6-7","author":[{"family":"Yoon","given":"J."},{"family":"Amy","given":"G."},{"family":"Yoon","given":"Y."}],"issued":{"date-parts":[["2005"]]}},{"id":991,"uris":["http://zotero.org/groups/945096/items/IIJW6E8Q"],"uri":["http://zotero.org/groups/945096/items/IIJW6E8Q"],"itemData":{"id":991,"type":"article-journal","title":"Determination of perchlorate rejection and associated inorganic fouling (scaling) for reverse osmosis and nanofiltration membranes under various operating conditions","container-title":"Journal of Environmental Engineering","page":"726-733","author":[{"family":"Yoon","given":"J."},{"family":"Yoon","given":"Y."},{"family":"Amy","given":"G."},{"family":"Her","given":"N."}],"issued":{"date-parts":[["2005",5]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. While water quality affects process design (e.g., recovery rate, cleaning frequency, and antiscalant selection), it has relatively little effect on perchlorate removal effectiveness of reverse osmosis membranes. Reverse osmosis generates a relatively large concentrate stream, which will contain perchlorate as well as other rejected dissolved solids, which will require disposal. The large concentrate stream also means less treated water is available for distribution (e.g., 70 to 85 percent of source water), which is a disadvantage for systems with limited water supply. Because reverse osmosis can increase the corrosivity of the treated water, it may require post-treatment or blending with bypass water.

Reverse osmosis can, however, remove co-occurring contaminants including arsenic and chromium-VI (Amy, Yoon, and Amy, 2005).

B. What are the Small System Compliance Technologies?

The EPA is proposing the SSCT shown in [REF _Ref529958951 \h]. The table shows which of the BAT listed above are also affordable for each small system size category listed in Section 1412(b)(4)(E)(ii) of the SDWA. The Agency identified these technologies based on an analysis of treatment effectiveness and affordability [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"J9AlL73G","properties":{"formattedCitation":"(USEPA, 2018a)","plainCitation":"(USEPA, 2018a)","noteIndex":0},"citationItems":[{"id":1210,"uris":["http://zotero.org/groups/945096/items/QBLZF9AR"],"uri":["http://zotero.org/groups/945096/items/QBLZF9AR"],"itemData":{"id":1210,"type":"article","title":"Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water.","publisher":"EPA ***-*-*-****","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Table X-[SEQ Table * ARABIC \s 1]: Proposed SSCT for Perchlorate Removal

System Size (Population Served)	Ion Exchange	Biological Treatment	Reverse Osmosis	Point-of-Use Reverse Osmosis
25-500	Yes	No	No	Yes
501-3,300	Yes	Yes	Yes	Yes
3,301-10,000	Yes	Yes	Yes	Not applicable[a]

a. For perchlorate, the EPA has determined that implementing and maintaining this option for systems larger than 3,300 people (greater than 1 MGD design flow) is likely to be impractical.

The SSCT listed in [REF _Ref529958951 \h] include a point-of-use (POU) version of reverse osmosis in addition to the ion exchange, biological treatment and reverse osmosis technologies described in the previous section. This technology can be used by small systems to comply with the proposed MCL and, therefore, meets the effectiveness requirement for an SSCT. For perchlorate removal, NSF/ANSI Standard 58: Reverse Osmosis Drinking Water Treatment Systems includes a protocol that requires a reverse osmosis unit to be able to reduce perchlorate from a challenge level of 130 μg/L to a target level of 4 μg/L (NSF, 2004). Organizations (e.g., NSF International, Underwriters Laboratories, Water Quality Association) provide third-party testing and certification that POU devices meet drinking water treatment standards. There are no perchlorate certification standards for other types of POU devices such as those using ion exchange media.

The operating principle for POU reverse osmosis devices is the same as centralized reverse osmosis: steric exclusion and electrostatic repulsion of ions from the charged membrane surface. In addition to a reverse osmosis membrane for dissolved ion removal, POU reverse osmosis devices often have a sediment pre-filter and a carbon filter in front of the reverse osmosis membrane, a 3- to 5-gallon treated water storage tank, and a carbon filter between the tank and the tap.

The EPA identified the SSCT using the affordability criteria methodology it developed for drinking water rules [ADDIN ZOTERO_ITEM CSL_CITATION
{"citationID":"LHgBHn5b","properties":{"formattedCitation":"(USEPA, 1998)","plainCitation":"(USEPA,

1998)","noteIndex":0},"citationItems":[{"id":1215,"uris":["http://zotero.org/groups/945096/items/399QNBY4"],"uri":["http://zotero.org/groups/945096/items/399QNBY4"],"itemData":{"id":1215,"type":"article","title":"Variance Technology Findings for Contaminants Regulated Before 1996","publisher":"EPA 815–R– 98–003. September","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["1998"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The analysis method is a comparison of estimated incremental household costs for perchlorate treatment to an expenditure margin, which is the difference between baseline household water costs and a threshold equal to 2.5% of median household income. [REF _Ref529959037 \h] shows the expenditure margins derived for the analysis. These margins show the cap on affordable incremental annual expenditures.

Table X-[SEQ Table * ARABIC \s 1]: Expenditure Margins for SSCT Affordability Analysis

System Size (Population Served)	Median Household Income[a] (a)	Affordability Threshold[b] (b) = 2.5% x a	Baseline Water Cost[c] (c)	Expenditure Margin (d) = b - c
25-500	$52,791	$1,320	$341	$979
501-3,300	$51,093	$1,277	$395	$883
3,301-10,000	$55,975	$1,399	$412	$987

Source: *Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water* [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"2scXqyv0","properties":{"formattedCitation":"(USEPA, 2018a)","plainCitation":"(USEPA, 2018a)","noteIndex":0},"citationItems":[{"id":1210,"uris":["http://zotero.org/groups/945096/items/QBLZF9AR"],"uri":["http://zotero.org/groups/945096/items/QBLZF9AR"],"itemData":{"id":1210,"type":"article","title":"Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water.","publisher":"EPA ***-*-*-****","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

a. MHI based on U.S. Census 2010 American Community Survey (ACS) 5-year estimates [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"x096Tc8Y","properties":{"formattedCitation":"(U.S. Census Bureau, 2010)","plainCitation":"(U.S. Census Bureau, 2010)","noteIndex":0},"citationItems":[{"id":1225,"uris":["http://zotero.org/groups/945096/items/WJ35QNBT"],"uri":["http://zotero.org/groups/945096/items/WJ35QNBT"],"itemData":{"id":1225,"type":"article","title":"American Community Survey, 5-year Estimates (2006-2010)","author":[{"family":"U.S. Census Bureau","given":""}],"issued":{"date-parts":[["2010"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] stated in 2010 dollars, adjusted to 2017 dollars using the CPI (for all items) for areas under 50,000 persons [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"7Rg9m81J","properties":{"formattedCitation":"(Bureau of Labor Statistics (BLS), 2018b)","plainCitation":"(Bureau of Labor Statistics (BLS), 2018b)","noteIndex":0},"citationItems":[{"id":1226,"uris":["http://zotero.org/groups/945096/items/GTI7H6YK"],"uri":["http://zotero.org/groups/945096/items/GTI7H6YK"],"itemData":{"id":1226,"type":"article","title":"CPI--All Urban Consumers (all items), for areas under 50,000 persons","author":[{"family":"Bureau of Labor Statistics (BLS)","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].
b. Affordability threshold equals 2.5 percent of MHI.
c. Household water costs derived from 2006 Community Water System Survey [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"fS2Ibu6t","properties":{"formattedCitation":"(USEPA, 2009c)","plainCitation":"(USEPA, 2009c)","noteIndex":0},"citationItems":[{"id":163,"uris":["http://zotero.org/groups/945096/items/DZNAAV6M"],"uri":["http://zotero.org/groups/945096/items/DZNAAV6M"],"itemData":{"id":163,"type":"article","title":"2006 Community Water System Survey - Volume II: Detailed Tables and Survey Methodology","URL":"https://www.epa.gov/dwstandardsregulations/community-water-system-survey","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2009",5]]},"accessed":{"date-parts":[["2018",8,17]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], based on residential revenue per connection within each size category, adjusted to 2017 dollars based on the CPI (for all items) for areas under 50,000 persons.

[REF _Ref529959069 \h] shows the estimates of per-household costs by treatment technology and size category generated using the treatment cost method described in section XII.B as well as *Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water* [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"z6GYvRh1","properties":{"formattedCitation":"(USEPA, 2018a)","plainCitation":"(USEPA, 2018a)","noteIndex":0},"citationItems":[{"id":1210,"uris":["http://zotero.org/groups/945096/items/QBLZF9AR"],"uri":["http://zotero.org/groups/945096/items/QBLZF9AR"],"itemData":{"id":1210,"type":"article","title":"Best Available Technologies and Small System Compliance

Technologies for Perchlorate in Drinking Water.","publisher":"EPA ***-*-*-****","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] and *Technologies and Costs for Treating Perchlorate-Contaminated Waters* [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"18aKvRLD","properties":{"formattedCitation":"(USEPA, 2018f)","plainCitation":"(USEPA, 2018f)","noteIndex":0},"citationItems":[{"id":147,"uris":["http://zotero.org/groups/945096/items/VUJUPN7L"],"uri":["http://zotero.org/groups/945096/items/VUJUPN7L"],"itemData":{"id":147,"type":"article","title":"Technologies and Costs for Treating Perchlorate-Contaminated Waters","publisher":"EPA ***-*-*-****","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Costs in bold font do not exceed the corresponding expenditure margin and, therefore, meet the SSCT affordability criterion. Therefore, the EPA has determined that there are affordable small system compliance technologies available and the Agency is not proposing any variance technologies.

Table X-[SEQ Table * ARABIC \s 1]: Annual Incremental Cost Estimates for SSCT Affordability Analysis

System Size (Population Served)	Ion Exchange	Biological Treatment	Reverse Osmosis	Point-of-Use Reverse Osmosis
25-500	**$378 to $610**	$2,146 to $3,709	$2,272 to $2,671	**$265 to $271**
501-3,300	**$98 to $148**	**$324 to $566**	**$561 to $688**	**$250 to $251**
3,301-10,000	**$104 to $153**	**$211 to $315**	**$431 to $493**	Not applicable[a]

Source: *Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water* [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"8y1WSJT4","properties":{"formattedCitation":"(USEPA, 2018a)","plainCitation":"(USEPA, 2018a)","noteIndex":0},"citationItems":[{"id":1210,"uris":["http://zotero.org/groups/945096/items/QBLZF9AR"],"uri":["http://zotero.org/groups/945096/items/QBLZF9AR"],"itemData":{"id":1210,"type":"article","title":"Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water.","publisher":"EPA ***-*-*-****","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], which describes the different WBS model input assumptions that result in ranges of per-household costs shown; bold font indicates cost estimates that do not exceed the corresponding expenditure margin.
a. For perchlorate, the EPA has determined that implementing and maintaining a POU program for systems larger than 3,300 people (greater than 1 MGD design flow) is likely to be impractical.

XI. Rule Implementation and Enforcement

A. What are the Requirements for Primacy?

This section describes the regulations and other procedures and policies primacy entities must adopt, or have in place, to implement the proposed perchlorate rule. States must continue to meet all other conditions of primacy in 40 CFR part 142. Section 1413 of the SDWA establishes requirements that primacy entities (States or Indian Tribes) must meet to maintain primary enforcement responsibility (primacy) for its public water systems. These include: (1) Adopting drinking water regulations that are no less stringent than federal NPDWRs in effect under sections 1412(a) and 1412(b) of the Act, (2) Adopting and implementing adequate procedures for enforcement, (3) Keeping records and making reports available on activities that the EPA requires by regulation, (4) Issuing variances and exemptions (if allowed by the State) under conditions no less stringent than allowed by SDWA Sections 1415 and 1416, and (5) Adopting and being capable of implementing an adequate plan for the provision of safe drinking water under emergency situations.

40 CFR part 142 sets out the specific program implementation requirements for States to obtain primacy for the Public Water Supply Supervision Program, as authorized under section 1413 of the Act.

To implement the perchlorate rule, States would be required to adopt revisions at least as stringent as the proposed provisions in 40 CFR 141.6 (Effective Dates); 40 CFR 141.23 (Inorganic chemical sampling and analytical requirements); 40 CFR 141.51 (Maximum contaminant level goals for inorganic contaminants); 40 CFR 141.60 (Effective Dates); 40 CFR 141.62 (Maximum contaminant levels for inorganic contaminants); Appendix A to Subpart O ([Consumer Confidence Report] Regulated contaminants); Appendix A to Subpart Q (NPDWR violations and other situations requiring public notice); Appendix B to Subpart Q (Standard health effects language for public notification); and 40 CFR 142.62 (Variances and exemptions from the maximum contaminant levels for organic and inorganic contaminants). Under 40 CFR 142.12(b), all primacy States/territories/tribes would be required to submit a revised program to the EPA for approval within two years of promulgation of any final perchlorate NPDWR or could request an extension of up to two years in certain circumstances.

B. What are the State Record Keeping Requirements?

The current regulations in 40 CFR 142.14 require States with primary enforcement responsibility (i.e., primacy) to keep records of analytical results to determine compliance, system inventories, sanitary surveys, State approvals, vulnerability and waiver determinations, monitoring requirements, monitoring frequency decisions, enforcement actions, and the issuance of variances and exemptions. The State record keeping requirements remain unchanged and would apply to perchlorate as with any other regulated contaminant.

C. What are the State Reporting Requirements?

Currently, States must report to the EPA information under 40 CFR 142.15 regarding violations, variances and exemptions, enforcement actions and general operations of State public water supply programs. The State reporting requirements remain unchanged and would apply to perchlorate as with any other regulated contaminant. However, the perchlorate MCL could result in a greater frequency of reporting by certain states. See discussion of Paperwork Reduction Act compliance in Section XVI for more information.

XII. Health Risk Reduction Cost Analysis

Section 1412(b)(3)(C) of the 1996 Amendments to the SDWA requires the EPA to prepare a Health Risk Reduction and Cost Analysis (HRRCA) in support of any NPDWR that includes an MCL. This section addresses the HRRCA requirements as indicated:

- Quantifiable and non-quantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level (Sections XII.C and XII.D);
- Quantifiable and non-quantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the MCL, excluding benefits resulting from compliance with other proposed or promulgated regulations (Section XII.C);

- Quantifiable and non-quantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the MCL, including monitoring, treatment, and other costs, and excluding costs resulting from compliance with other proposed or promulgated regulations (Section XII.B and XII.D);
- The incremental costs and benefits associated with each alternative MCL considered (Section XII.D);
- The effects of the contaminant on the general population and on groups within the general population, such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other sensitive populations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population (Section XII.C and Section III);
- Any increased health risk that may occur as the result of compliance, including risks associated with co-occurring contaminants (Section XII.C); and
- Other relevant factors, including the quality and extent of the information, the uncertainties in the analysis, and factors with respect to the degree and nature of the risk (Section XII.E).

A. Identifying Affected Entities

If the EPA issues a final NPDWR for perchlorate, it would affect the following entities: CWSs and NTNCWSs that must meet the proposed MCL and monitoring and reporting requirements; and primacy agencies that must adopt and enforce the MCL as well as the monitoring and reporting requirements. All of these entities would incur costs, including administrative costs, monitoring and reporting costs, and – in a limited number of cases – costs to reduce perchlorate levels in drinking water to meet the proposed MCL using treatment or nontreatment options. Section B below summarizes the method the EPA used to estimate these costs.

The systems that reduce perchlorate concentrations will reduce associated health risks. The EPA developed a method to estimate the potential benefits of reduced perchlorate exposure among the service populations of systems with elevated baseline perchlorate levels. Section C below summarizes this method used to estimate these benefits.

Section D below provides the cost and benefit estimates. The EPA prepared the Health Risk Reduction Cost Analysis of the Proposed Perchlorate Rule (USEPA, 2019a), which is available in the docket for the proposed rule. Section XIII summarizes and discusses key uncertainties in the cost and benefit analyses.

B. Method for Estimating Costs

Some costs associated with an NPDWR are incurred by all CWS and NTNCWS (e.g. monitoring and reporting) while others are only incurred by systems with perchlorate levels exceeding the MCL. The EPA estimated costs for CWS and NTNCWS to monitor and report perchlorate levels and also estimated the costs for a subset of public water systems with perchlorate levels greater than the proposed MCL to install and operate treatment. The EPA assumed that affected water systems would adopt ion exchange treatment because it is the most cost-effective treatment option and easy to operate on a 'throw-away' basis. If site-specific nontreatment options are available and lower cost, then this assumption might overstate costs. The EPA also estimated the costs for States and other primacy agencies to assure systems implement the rule and to report information to the EPA.

The EPA estimated initial costs for all CWS and NTNCWS operators to read and understand the rule and provide training to their staff to implement the proposed rule. The EPA also estimated the recurring costs for all CWS and NTNCWS operators to conduct monitoring, report results, and apply for waivers. For the purpose of these estimates, the EPA assumed that both small and large systems would require the same amount of time to read the rule, apply for a waiver, and collect a water sample but that it would take large systems twice as long to provide initial training to their staff. Table XII-1 summarizes the frequency and labor hour assumptions for this analysis.

Table XII-1: Labor Hours for Drinking Water Systems Administrative and Monitoring Requirements

Activity	Frequency	Small System Hours	Large System Hours
Read the rule	one time per system	4	4
Provide initial training	one time per system	16	32
Apply to State for monitoring waiver	once every 9 years per eligible system	16	16
Collect a single finished water sample[1]	per monitoring event	1	1

Source (USEPA, 2000a). The EPA's cost analysis reflects full MCL compliance and therefore the EPA did not estimate Tier 1 notification costs.

1. The estimate is per sample. Therefore, a system conducting a year of quarterly monitoring at three entry points incurs a total of 12 hours of labor to complete the task (3 entry points x 4 samples x 1 hour per sample).

Systems will incur monitoring costs over the analysis period. The EPA estimated monitoring frequency based on the proposed initial monitoring requirements, the standard monitoring framework requirements for inorganic contaminants, and the proposed implementation schedule. The estimated number of monitoring samples over the analysis period shown in Table XII-2 reflect the following phases:

1. Initial monitoring; four quarterly samples at every CWS and NTNCWS entry point.

2. Preliminary regular monitoring before waiver application: three regular monitoring samples for every CWS and NTNCWS entry point (collected annually at surface water system entry points and triennially at ground water system entry points).

3. Long-term monitoring at either (a) regular monitoring frequency for entry points at systems not granted waivers (60% of surface water system and 10% of ground water systems), or (b) reduced monitoring frequency for entry points at systems receiving waivers from primacy agencies (40% of surface water systems and 90% of ground water systems), which is one sample during every nine-year compliance monitoring cycle.

Table XII-2: Estimates of Compliance Monitoring Samples by Phase and System Type, Size, and Source Water

Monitoring Phase (sampling frequency)	System Type, Size, and Source Water	Number of Entry Points[1]	Aggregate Samples[2]
1. Initial monitoring (4 quarterly samples in one year)	All CWS and NTNCWS	92,656	370,624
2. Preliminary regular monitoring (3 annual entry point samples for surface water systems and 3 triennial entry point samples for ground water systems)	All CWS and NTNCWS	92,654	277,962
3a. Long-term monitoring, no waiver (annual entry point samples)	60% of large surface water CWS	3,324	86,424
	60% of small surface water CWS and all surface water NTNCWS	6,064	139,472
3a. Long-term monitoring, no waiver (triennial entry point samples)	10% of large ground water CWS	680	4,080
	10% of small ground water CWS and all ground water NTNCWS	7,021	35,105
3b. Long-term monitoring, waiver (1 sample every 9 years)	40% of large surface water CWS	2,216	4,432
	40% of small surface water CWS and all surface water NTNCWS	4,043	8,086

Monitoring Phase (sampling frequency)	System Type, Size, and Source Water	Number of Entry Points[1]	Aggregate Samples[2]
3b. Long-term monitoring, waiver (1 sample every 9 years)	90% of large ground water CWS	6,117	12,234
	90% of small ground water CWS and all ground water NTNCWS	63,189	63,189

Source: Perchlorate Benefit-Cost Analysis Spreadsheet available in the proposed rule docket (EPA-HQ-OW-2018-0780).

1. The EPA estimated a total of 92,656 entry points based on the total number of potentially affected systems in SDWIS/FED and the average number of entry points per system in the UCMR 1 data by size category and source water. The initial monitoring phase includes all entry points. The EPA assumed that the two entry points with MCL exceedances at the proposed MCL of 56 μg/L would continue to take quarterly samples for the duration of the analysis period, for a total of 232 samples. Thus, they are excluded from the estimates for the subsequent phases of regular and long-term monitoring. Primacy agencies may, however, allow monitoring to return to a regular schedule if treatment process operation can reliably and consistently reduce perchlorate below the MCL.

2. For Phase 3, the estimate of aggregate samples is the product of the number of entry points and the frequency of sampling during the remaining years of the analysis period. For example, large surface water CWS without a waiver conduct long-term annual monitoring for 26 years because they complete preliminary regular monitoring in year 9. In contrast, large ground water CWS without a waiver begin long-term triennial monitoring in year 16 because their preliminary regular monitoring phase lasts for 9 years (3 triennial samples) instead of 3 years (3 annual samples). The estimates also reflect schedule differences by size because large CWS begin monitoring schedules three years earlier than small CWS and all NTNCWS.

To estimate costs to CWSs and NTNCWSs associated with time spent on compliance monitoring and other administrative costs, the EPA generally uses the labor rate[13] for full-time treatment plant operators in CWSs from USEPA [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"5g8IJ6Eh","properties":{"formattedCitation":"(2011)","plainCitation":"(2011)","noteIndex":0},"citationItems":[{"id":992,"uris":["http://zotero.org/groups/945096/items/FHCVSMRC"],"uri":["http://zotero.org/groups/945096/items/FHCVSMRC"],"itemData":{"id":992,"type":"article","title":"Labor Cost for National Drinking Water Rules","author":[{"family":"USEPA","given":""}],"issued":{"date-

[13] Updated to 2017$ using the BLS Employment Cost Index for Total Compensation for Private industry workers in Utilities.

parts":[["2011"]]}},"suppress-author":true}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], which vary based on the size of the system. The EPA calculated a weighted average fully loaded hourly wage rate for water systems of $34.71.

Additionally, the EPA assumed that systems will incur an average analytical cost of $64 per sample, which is the average cost per sample obtained from multiple laboratories for perchlorate quantitation using Method 314.0.

To estimate treatment cost, the EPA utilized the occurrence data described in Section VI to estimate the number of system entry points that exceed the proposed and alternative MCLs. The EPA estimated costs that those water systems would incur to install and maintain treatment using its work breakdown structure (WBS) cost estimating models. The WBS models are spreadsheet-based engineering models for individual treatment technologies, linked to a central database of component unit costs. The WBS approach involves breaking a process down into discrete components for the purpose of estimating costs and produce a comprehensive assessment of the capital and operating requirements for a treatment system[14]. The EPA used the WBS models to generate total capital and O&M cost estimates for each technology and nontreatment option for up to 49 different system flow rates. The EPA generated separate estimates that correspond to different water sources (groundwater or surface water), three different cost levels (low, mid, and high), and different technology-specific scenarios (e.g.,

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[14] The document *Technologies and Costs for Treating Perchlorate-Contaminated Waters* (USEPA, 2018c) contains more complete discussion of the WBS models and the cost estimating approach.

105,000 or 170,000 bed volumes for ion exchange). The EPA used the mid-cost estimates for ion exchange to generate expected costs for all entry points requiring perchlorate removal. This technology cost-effectively removes perchlorate, but its ability to remove co-occurring contaminants depends on influent characteristics and process design. Therefore, the EPA did not assume that treatment might result in ancillary quantifiable or non-quantifiable benefits of removing co-occurring ions such as nitrate. Treatment costs include waste disposal for spent resin, but do not include post-treatment costs for corrosion control because blending rates at most entry points should not result in much chloride addition or changes in corrosivity.

For purposes of estimating the costs and benefits, the EPA assumed that CWSs and NTNCWSs in California and Massachusetts would not incur additional cost or realize benefits because these States currently regulate perchlorate at a more stringent level than the proposed MCL and alternative MCL. For each entry point in the UCMR 1 dataset outside of these two States, the EPA compared the maximum observed perchlorate concentration to the MCL to identify those that have an exceedance of the proposed MCL. The EPA assumed that these entry points would incur costs for an additional confirmation sample and would need to implement treatment to meet the MCL. For each entry point, the EPA estimated the design flow and the average flow by service populations based on the Agency's prior analysis of the relationships between these values (USEPA, 2000b). The Agency assumed blending of treated water and untreated water would be used to meet an average treatment target equal to 80 percent of the MCL (for an MCL of 56 μg/L the blending target would be 45 μg/L) given a 95 percent removal effectiveness until perchlorate breakthrough. The Agency applied the capital cost and O&M cost curves from the WBS models to the design and average flows adjusted for blending. When small systems in the UCMR 1 sample incurred treatment costs, the EPA extrapolated the costs on a per capita basis to the estimate of national population exposure derived using the small system population sampling weights.

For the primacy agencies that will implement and enforce the rule (including 49 States, one tribal nation and 5 territories), the EPA estimated upfront costs incurred during the three years between rule promulgation and the effective date to read and understand the rule, adopt regulatory changes, and provide training to CWSs and NTNCWSs and Agency staff. Primacy agencies will also have recurring costs to review waiver applications and monitoring reports. Table XII-3 summarizes the labor hour assumptions for these activities. The EPA requests comments on these assumptions.

Table XII-3: Labor Hours for Primacy Agency Administrative Requirements

Activity	Frequency	Hours
Read and understand the rule, adopt regulatory changes[1]	one time per Agency	416
Provide initial training and assistance to water systems[2]	total per Agency	2,080
Provide initial training to staff[2]	total per Agency	250
Review waiver applications	once every 9 years per eligible system	8
Review monitoring reports	per monitoring event	1

Source (USEPA, 2000a)

1. The EPA assumed that two States that already regulate perchlorate in drinking water would not incur the incremental burdens in this table to regulate perchlorate under the proposed rule because they already incur baseline costs for perchlorate regulation including monitoring costs. The Agency assumed, however, that the two States would incur an average of 40 hours to confirm that their existing requirements are at least as protective as the proposed rule.
2. The EPA assumed that all training hours occur in a single year, although the hours may actually occur over time. The total hour estimates are average values across States.

State labor rates are based on the mean hourly wage rate from Bureau of Labor Statistics (BLS) Standard Occupational Classification code 19-2041 (State Government –Environmental

Scientists and Specialists, Including Health). Wages are loaded using a factor calculated from the BLS Employer Costs for Employee Compensation report [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"C1A8zUkj","properties":{"formattedCitation":"(Bureau of Labor Statistics (BLS), 2016 Table 3)","plainCitation":"(Bureau of Labor Statistics (BLS), 2016 Table 3)","noteIndex":0},"citationItems":[{"id":984,"uris":["http://zotero.org/groups/945096/items/L8X3BDZ9"],"uri":["http://zotero.org/groups/945096/items/L8X3BDZ9"],"itemData":{"id":984,"type":"webpage","title":"Employer Cost for Employee Compensation -- September 2016","author":[{"literal":"Bureau of Labor Statistics (BLS)"}],"issued":{"date-parts":[["2016"]]}},"label":"book","suffix":"Table 3"}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], for a fully loaded hourly wage rate for States of $50.67. The EPA requests comments on these labor rate assumptions.

The proposed rule provides three years between the effective dates and compliance dates for systems. For the purpose of estimating costs, the EPA assumed that large CWSs would phase in administrative costs, including initial monitoring, and upfront administrative costs uniformly over the 3 years following the effective date (i.e., years 4 to 6 of the analysis period). Similarly, the EPA assumed that small CWSs and NTNCSs will phase in these costs over the subsequent three-year period (i.e., years 7 to 9 of the analysis period). The EPA assumed that, within these periods, all systems would conduct initial monitoring – one year of quarterly monitoring to determine whether perchlorate concentrations are consistently and reliably below the proposed MCL. Thereafter, systems with MCL exceedances would continue to monitor quarterly, while systems below the MCL that obtain waivers will monitor annually for three years (surface water systems) or triennially for 9 years (ground water systems), then incur costs for a waiver application. Thereafter, these systems will continue reduced monitoring - once every nine years - under subsequent waivers. Systems that are below the MCL without waivers will monitor once per year (surface water systems) or once every three years (groundwater). Consistent with [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"mnzEXxZK","properties":{"formattedCitation":"(USEPA, 2008b)","plainCitation":"(USEPA, 2008b)","dontUpdate":true,"noteIndex":0},"citationItems":[{"id":998,"uris":["http://zotero.org/groups/945096/items/QSXYHBID"],"uri":["http://zotero.org/groups/945096/items/QSXYHBID"],"itemData":{"id":998,"type":"article","title":"Draft Information Collection Request for the Disinfectants/Disinfection Byproducts, Chemical, and Radionuclides Rule","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2008",6]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], the EPA assumed that 90% of groundwater and 40% of surface water systems that have all entry points below the MCL would obtain waivers.

The EPA estimated the costs over a 35-year analysis period, which includes a 3-year period prior to the effective date to allow for State rule adoption activities, a 3-year period after the effective date to allow initial monitoring among large CWSs, and a 3-year period after that to allow initial monitoring for small CWSs and NTNCWSs. Evaluating costs over 35 years covers a full life cycle of the capital investments that large systems make in the 6th year; the WBS estimates of composite useful life of the equipment and infrastructure investment is approximately 30 years. The EPA assumed that treatment modifications will be completed in the final year of the initial monitoring period (i.e., year 6 of the analysis for large CWSs and year 9 for small CWSs and NTNCWSs). The EPA calculated the present value of total costs in each year of the analysis period and discounted to year 1 using both a 3% and 7% discount rate and annualized total present value of costs at the same rates over 35 years to obtain a constant total annual cost estimate to compare to total annual benefits.

Water systems typically recover costs through increased household rates, resulting in increased costs at the household level[15]. To calculate the magnitude of the cost increase for systems that exceed the proposed MCL or alternative MCL, the EPA first estimated the number of households that may incur costs as a result of the rule based on the population served by affected CWSs and NTNCWSs and the average household size [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"Q6RKolIZ","properties":{"formattedCitation":"(U.S. Census Bureau, 2017b)","plainCitation":"(U.S. Census Bureau, 2017b)","noteIndex":0},"citationItems":[{"id":1000,"uris":["http://zotero.org/groups/945096/items/CGU3LT9N"],"uri":["http://zotero.org/groups/945096/items/CGU3LT9N"],"itemData":{"id":1000,"type":"article","title":"Average Household Size of Occupied Housing Units by Tenure. American Community Survey 1-Year Estimates: Table B25010","author":[{"family":"U.S.

[15] For systems with monitoring costs only, household-level costs will be negligible.

Census Bureau","given":""}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The EPA divided the total annual system-level costs by the number of households served by the system.

C. Method for Estimating Benefits

The EPA has taken an approach in evaluating the benefits for perchlorate that is consistent with the SAB's recommendations for the methodology to inform the MCLG for perchlorate. This approach involves a) using a BBDR model to estimate the impact of perchlorate on maternal thyroid hormone levels during the first trimester of pregnancy, and b) using a dose-response function from the epidemiological literature to model the relationship between altered maternal thyroid hormone levels and offspring IQ. Currently available science has limited this quantitative benefits assessment to the relationship between perchlorate and IQ. Given that alterations in thyroid hormones have been associated with other adverse outcomes, including reproductive outcomes (Alexander et al., 2017; Hou et al., 2016; Maraka et al., 2016) and effects on cardiovascular systems (Asvold et al., 2012; Sun et al., 2017) there are likely non-quantified benefits of risk reductions for other endpoints or reduced exposure to co-occurring contaminants, which are addressed below. Uncertainties regarding the quantifiable benefits are also addressed below.

The population impacted by the rule for which benefits can be quantified is specific to live births from mothers who were served by a CWS or NTNCWS with perchlorate concentrations above the potential MCLs. To determine the nationwide population of children that will experience a quantifiable benefit of avoided IQ decrements from reducing maternal perchlorate exposure during pregnancy, the EPA first estimated the total population being served by systems above the MCL based on data from UCMR 1. The EPA then multiplied the total population served for each affected CWS and NTNCWS by the proportion of women of childbearing age (aged 15-44) in the US, which is 19.7 percent [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"rCNbGglo","properties":{"formattedCitation":"(U.S. Census Bureau, 2017a)","plainCitation":"(U.S. Census Bureau, 2017a)","noteIndex":0},"citationItems":[{"id":189,"uris":["http://zotero.org/groups/945096/items/ZM7S6H44"],"uri":["http://zotero.org/groups/945096/items/ZM7S6H44"],"itemData":{"id":189,"type":"article","title":"Annual estimates of the resident population by single year of age and sex for the United States: April 1, 2010 to July 1, 2016.","URL":"https://www.census.gov/data/datasets/2016/demo/popest/nation-detail.html#ds","author":[{"literal":"U.S. Census Bureau"}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The number of women of child-bearing age for each entry point was then multiplied by the annual number of live births in the US, or 62 births per 1,000 women (6.2 percent) [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"7XfZyKhY","properties":{"formattedCitation":"(Martin, Hamilton, & Osterman, 2017)","plainCitation":"(Martin, Hamilton, & Osterman, 2017)","noteIndex":0},"citationItems":[{"id":186,"uris":["http://zotero.org/groups/945096/items/MY6LPDKD"],"uri":["http://zotero.org/groups/945096/items/MY6LPDKD"],"itemData":{"id":1

86,"type":"article","title":"Births in the United States, 2016. NCHS Data Brief No. 287","URL":"https://www.cdc.gov/nchs/data/databriefs/db287.pdf","author":[{"family":"Martin","given":"J.A."},{"family":"Hamilton","given":"B.E."},{"family":"Osterman","given":"M.J.K"}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

The EPA used a two-step dose-response model to estimate health benefits of a reduction in perchlorate exposure as a result of regulating perchlorate in drinking water not to exceed the proposed MCL of 56 μg/L and alternative MCLs of 18 μg/L and 90 μg/L. The first step relates changes in perchlorate to changes in maternal free-thyroxine (fT4) during the first trimester of pregnancy using the EPA's BBDR model. Because the dose-response relationship between perchlorate exposure and maternal fT4 is dependent on maternal iodine intake status, this first-step analysis is repeated for several categories of iodine intake. For the BBDR simulations, the EPA used the 90th percentile ingestion rate to be consistent with the MCLG modeling approach, which may overstate the exposure in the simulation.

The second step of the dose-response model subsequently relates the predicted changes in maternal fT4 from the BBDR model to changes in child IQ using the function estimated in the EPA independent analysis of the [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"iqyVRL6z","properties":{"formattedCitation":"(Korevaar et al., 2016)","plainCitation":"(Korevaar et al., 2016)","dontUpdate":true,"noteIndex":0},"citationItems":[{"id":43,"uris":["http://zotero.org/groups/945096/items/B968J6XI"],"uri":["http://zotero.org/groups/945096/items/B968J6XI"],"itemD ata":{"id":43,"type":"article-journal","title":"Association of maternal thyroid function during early pregnancy with offspring IQ and brain morphology in childhood: a population-based prospective cohort study","container-title":"The Lancet Diabetes & Endocrinology","page":"35-43","volume":"4","issue":"1","source":"ScienceDirect","abstract":"SummaryBackground\nThyroid hormone is involved in the regulation of early brain development. Since the fetal thyroid gland is not fully functional until week 18–20 of pregnancy, neuronal migration and other crucial early stages of intrauterine brain development largely depend on the supply of maternal thyroid hormone. Current clinical practice mostly focuses on preventing the negative consequences of low thyroid hormone concentrations, but data from animal studies have shown that both low and high concentrations of thyroid hormone have negative effects on offspring brain development. We aimed to investigate the association of maternal thyroid function with child intelligence quotient (IQ) and brain morphology.\nMethods\nIn this population-based prospective cohort study, embedded within the Generation R Study (Rotterdam, Netherlands), we investigated the association of maternal thyroid function with child IQ (assessed by non-verbal intelligence tests) and brain morphology (assessed on brain MRI scans). Eligible women were those living in the study area at their delivery date, which had to be between April 1, 2002, and Jan 1, 2006. For this study, women with available serum samples who presented in early pregnancy (<18 weeks) were included. Data for maternal thyroid-stimulating hormone, free thyroxine, thyroid peroxidase antibodies (at weeks 9–18 of pregnancy), and child IQ (assessed at a median of 6·0 years of age [95% range 5·6–7·9 years]) or brain MRI scans (done at a median of 8·0 years of age [6·2–10·0]) were obtained. Analyses were adjusted for potential confounders including concentrations of human chorionic gonadotropin and child thyroid-stimulating hormone and free thyroxine.\nFindings\nData for child IQ were available for 3839 mother–child pairs, and MRI scans were available from 646 children. Maternal free thyroxine concentrations showed an inverted U-shaped association with child IQ (p=0·0044), child grey matter volume (p=0·0062), and cortex volume (p=0·0011). For both low and high maternal free thyroxine concentrations, this association corresponded to a 1·4–3·8 points reduction in mean child IQ. Maternal thyroid-stimulating hormone was not associated with child IQ or brain morphology. All associations remained similar after the exclusion of women with overt hypothyroidism and overt hyperthyroidism, and after adjustment for concentrations of human chorionic gonadotropin, child thyroid-stimulating hormone and free thyroxine or thyroid peroxidase antibodies (continuous or positivity).\nInterpretation\nBoth low and high maternal free thyroxine concentrations during pregnancy were associated with lower child IQ and lower grey matter and cortex volume. The association between high maternal free thyroxine and low child IQ suggests that levothyroxine therapy during pregnancy, which is often initiated in women with subclinical hypothyroidism during pregnancy, might carry the potential risk of adverse child neurodevelopment outcomes when the aim of treatment is to achieve high-normal thyroid function test results.\nFunding\nThe Netherlands Organisation for Health Research and Development (ZonMw) and the European Community's Seventh Framework Programme.","DOI":"10.1016/S2213-8587(15)00327-7","ISSN":"2213-8587","shortTitle":"Association of maternal thyroid function during early pregnancy with offspring IQ and brain morphology in childhood","journalAbbreviation":"The Lancet Diabetes & Endocrinology","author":[{"family":"Korevaar","given":"Tim I

M"},{"family":"Muetzel","given":"Ryan"},{"family":"Medici","given":"Marco"},{"family":"Chaker","given":"Layal"},{"family":"Jaddoe","given":"Vincent W V"},{"family":"Rijke","given":"Yolanda B","non-dropping-particle":"de"},{"family":"Steegers","given":"Eric A P"},{"family":"Visser","given":"Theo J"},{"family":"White","given":"Tonya"},{"family":"Tiemeier","given":"Henning"},{"family":"Peeters","given":"Robin P"}],"issued":{"date-parts":[["2016",1]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] study data. Ultimately, the changes in IQ are estimated for each impacted iodine intake group, and all of the impacted iodine intake groups' IQ decrements are averaged together based on the proportion of individuals in each iodine intake category. Table XII-4 shows the specific iodine intake groups and the proportion of non-pregnant women of childbearing age that fall into each group.

Table XII-4: Proportion of Population based on Maternal Iodine Intake Status

Iodine Intake Range (μg/ day) used for Benefits Analysis	Proportion of the population
0 to <55	7.14%
55 to <60	2.15%
60 to <65	1.06%
65 to < 70	1.86%
70 to <75	1.31%
75 to <80	3.10%
80 to <85	2.62%
85 to <90	1.20%
90 to <95	1.83%
95 to <100	2.94%
100 to <125	13.56%
125 to <150	9.08%
150 to <170	10.31%
170 to <300	24.47%
≥300	17.36%

Source: U.S. EPA (2019a).

These changes in child IQ are then monetized using the EPA's estimate of the value of an IQ point. This estimate reflects the discounted present value of lifetime income reductions attributable to a 1-point reduction in IQ at birth. Therefore, the present value depends on the discount rate. At a 3 percent discount rate, the estimate is $18,686 per IQ point; at a 7 percent discount rate the estimate is $3,631.

Other potential benefits not quantified or monetized include additional avoided health effects which cannot currently be monetized, improved public perception of water quality, as well as a possible reduction of other co-occurring contaminants that target the thyroid, such as nitrate, as a result of water treatment for removal of perchlorate. For example, all of the treatment technologies evaluated for this rule (ion exchange, biological treatment, and reverse osmosis) can also remove co-occurring nitrate from drinking water. Section XIII provides additional discussion of uncertainties in this analysis.

D. Comparison of Costs and Benefits

This section provides the estimates of costs and benefits that the EPA derived using the methods described above. It includes estimates for the proposed and alternative MCLs.

For the proposed MCL of 56 μg/L, Table XII-5 summarizes the total estimated cost of the proposed rule to water systems and primacy agencies, and Table XII-6 summarizes the estimated per-household cost for the system incurring treatment costs[16]. Table XII-7 summarizes the estimated benefits. In both instances, the estimates based on the UCMR 1 sample are also national estimates because treatment costs occur only at large systems; there are no small system treatment costs or related benefits to extrapolate.

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[16] For all households served by all of the systems subject to the monitoring costs as well as MCL compliance, the average annual cost is less than $0.20.

Table XII-5: Summary of Total Annualized Costs at MCL of 56 μg/L (Millions; 2017$)

Cost Component	3% Discount	7% Discount
Drinking Water Systems Treatment Costs	$0.65	$0.70
Drinking Water Systems Monitoring and Administration Costs[1]	$5.93	$6.38
Drinking Water Systems Costs Subtotal	$6.58	$7.07
State Administration Costs	$3.09	$3.20
Total Costs	$9.67	$10.28

Source: [ADDIN ZOTERO_ITEM CSL_CITATION
{"citationID":"00m0B8b8","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].
Detail may not sum to total because of independent rounding.
1. Costs include monitoring for all CWS and NTNCWS. Some consecutive systems that purchase 100% of their water from wholesale systems may not be required to monitor for perchlorate provided States allow integrated system agreements to include perchlorate among the monitoring requirements that the wholesale system fulfills for the consecutive system. The potential number of consecutive systems excluded from perchlorate monitoring depends on system and State decisions and, therefore, is unknown. Excluding monitoring costs for approximately 8,400 consecutive systems that do not report a water source facility (e.g., well or intake) in SDWIS/FED from the monitoring cost analysis reduces annualized monitoring costs by $0.8 million.

Table XII-6: Summary of Household-Level Annual Costs for Systems Treating to Comply with MCL at 56 μg/L (2017$)

Cost Range	3% Discount	7% Discount
Minimum	$11	$14
Average	$40	$47
Maximum	$69	$80

Source: [ADDIN ZOTERO_ITEM CSL_CITATION

{"citationID":"xTqTuaNv","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Table XII-7: Summary of Total Annualized Benefits of Avoided Lost IQ Decrements at MCL of 56 μg/L (Millions; 2017$)

Korevaar β distribution	Annual Delta IQ	3% Discount	7% Discount
Upper	243	$3.57	$0.60
Central	136	$2.00	$0.34
Lower	30	$0.44	$0.07

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"T7LDdiyn","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

For the alternative MCL of 18 μg/L, Table XII-8 summarizes the total cost of the proposed rule to water systems and primacy agencies, and Table XII-9 summarizes the per-household cost for systems requiring treatment, which vary across the systems. Table XII-10 summarizes the quantified benefits. At this threshold, one entry point for one small system in the UCMR 1 data had an exceedance. Therefore, the EPA extrapolated the treatment costs and benefits from the UCMR 1 estimates to national estimates based on sampling weights.

Table XII-8: Summary of Total Annualized Costs at MCL of 18 μg/L (Millions; 2017$)

Cost Component	3% Discount (UCMR 1)[1]	7% Discount (UCMR 1)[1]	3% Discount (National)[1]	7% Discount (National)[1]
Drinking Water Systems Treatment Costs	$6.92	$7.29	$7.92	$8.37
Drinking Water Systems Monitoring and Administration Costs	$5.94	$6.38	$5.94	$6.38
Drinking Water Systems Costs Subtotal	$12.85	$13.67	$13.86	$14.75
State Administration Costs	$3.09	$3.21	$3.09	$3.21
Total Costs	$15.95	$16.88	$16.95	$17.96

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"H6Rcd4Hf","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].
Detail may not sum to total because of independent rounding.

1. The EPA applied statistical sampling weights to the results to extrapolate small system results to national results. The entry point at which a measurement exceeds 18 μg/L is one of 20 in its sample stratum; no other sample in the stratum had a measurement of perchlorate greater than the minimum reporting level. The entry point population of 2,155 represents 5.31% of the total population served by the six UCMR 1 systems in the stratum (40,574). Currently, the stratum population of 775,000 accounts for 1.32% of the 58.7 million national population served by small systems. Thus, the UCMR 1 results indicate that 0.07% (5.31% x 1.32%) of small system customers (approximately 41,100) may be exposed to perchlorate greater than 18 μg/L. The EPA calculated per-capita costs for the system and extrapolated to national level based on this population estimate.
2. Costs include monitoring for all CWS and NTNCWS. Under 40 CFR 141.29 some consecutive systems that purchase 100% of their water from wholesale systems may not be required to monitor for perchlorate provided primacy agencies, with EPA concurrence, allow integrated system agreements to include perchlorate among the monitoring requirements that the wholesale system fulfills for the consecutive system. The potential number of consecutive systems excluded from perchlorate monitoring depends on system and primacy agency decisions and, therefore, is unknown. Excluding monitoring costs for approximately 8,400 consecutive systems that do not report a water source facility (e.g., well or intake) in SDWIS/FED from the monitoring cost analysis reduces annualized monitoring costs by $0.8 million.

Table XII-9: Summary of Household-Level Annual Costs for Systems Treating to Comply with the MCL at 18 μg/L (2017$)

Cost Range	3% Discount (UCMR 1)[1]	7% Discount (UCMR 1)[1]	3% Discount (National)[1]	7% Discount (National)[1]
Minimum	$18	$24	$18	$24
Average	$38	$46	$38	$46
Max	$72	$84	$72	$84

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"uu13kmuC","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

1. National cost estimates include extrapolation for one small system entry point to national estimates based on sampling weights. The per-household costs are the same for the sample and national extrapolations because the small system cost extrapolation occurs on a per-capita basis.

Table XII-10: Total and Annualized Benefits of Avoided Lost IQ Decrements at 18 μg/L (Millions; 2017$)

Korevaar β distribution	Annual Delta IQ		UCMR 1		National[1]	
	UCMR 1	National[1]	3% Discount	7% Discount	3% Discount	7% Discount
Upper	442	447	$6.50	$1.10	$6.56	$1.11
Central	248	251	$3.65	$0.62	$3.68	$0.62
Lower	54	55	$0.80	$0.13	$0.80	$0.14

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"EN9pibZj","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

1. The EPA applied statistical sampling weights to the results to extrapolate small system results to national results. The entry point at which a measurement exceeds 18 μg/L is one of 20 in its sample stratum; no other sample in the stratum had a measurement of perchlorate greater than the minimum reporting level. The entry point population of 2,155 represents 5.31% of the total population served by the six UCMR 1 systems in the stratum (40,574). Currently, the stratum population of 774,780 accounts for 1.32% of the 58.7 million national population served by small systems. Thus, the UCMR 1 results indicate that 0.07% (5.31% x 1.32%) of small system customers (approximately 41,100) may be exposed to perchlorate greater than 18 μg/L. The EPA assumed that this population would incur benefits equivalent to the sampled entry point's population.

For the alternative MCL of 90 μg/L, Table XII-11 summarizes the total cost of the proposed rule to water systems and primacy agencies, and Table XII-12 summarizes the per-household cost for systems requiring treatment, which vary across the systems. Table XII-13 summarizes the quantified benefits. At this threshold, no small systems in the UCMR 1 data had an exceedance. Therefore, treatment costs and benefits for the UCMR 1 data are the national estimates.

Table XII-11: Summary of Total Annualized Costs at MCL of 90 μg/L (Millions; 2017$)

Cost Component	3% Discount	7% Discount
Drinking Water Systems Treatment Costs	$0.49	$0.52
Drinking Water Systems Monitoring and Administration Costs[1]	$5.93	$6.37
Drinking Water Systems Costs Subtotal	$6.42	$6.89
State Administration Costs	$3.09	$3.20
Total Costs	$9.51	$10.10

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1. Costs include monitoring for all CWS and NTNCWS. Some consecutive systems that purchase 100% of their water from wholesale systems may not be required to monitor for perchlorate provided States allow integrated system agreements to include perchlorate among the monitoring requirements that the wholesale system fulfills for the consecutive system. The potential number of consecutive systems excluded from perchlorate monitoring depends on system and State decisions and, therefore, is unknown. Excluding monitoring costs for approximately 8,400 consecutive systems that do not report a water source facility (e.g., well or intake) in SDWIS/FED from the monitoring cost analysis reduces annualized monitoring costs by $0.8 million.

Table XII-12: Summary of Household-Level Annual Costs for Systems Treating to Comply with MCL at 90 μg/L (2017$)

Cost Range	3% Discount	7% Discount
Minimum	$65	$76
Average	$65	$76
Maximum	$65	$76

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Table XII-13: Summary of Total Annualized Benefits of Avoided Lost IQ Decrements at MCL of 90 µg/L (Millions; 2017$)

Korevaar β distribution	Annual Delta IQ	3% Discount	7% Discount
Upper	222	$3.26	$0.55
Central	124	$1.83	$0.31
Lower	27	$0.40	$0.07

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Table XII-14 provides a comparison of benefits and costs for three MCL values. First, the table shows the total annual costs and total annual benefits for each MCL. In all cases, the total costs are substantially higher than the potential range of quantifiable benefits. The table also shows the incremental impact on costs and benefits between an MCL of 56 µg/L and an MCL of 18 µg/L and between an MCL of 90 µg/L and 56 µg/L.

Section 1412(b)(4)(C) of the SDWA requires that when proposing a national primary drinking water regulation, "the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs." The infrequent occurrence of perchlorate at levels of health concern imposes high monitoring and administrative cost burdens on public water systems and the States. Based on a comparison of costs and benefits estimated at the proposed MCL of 56 μg/L using the best available science and data, the EPA Administrator has determined based upon the available information that the benefits of establishing an NPDWR for perchlorate do not justify the associated costs.

Under these circumstances, Section 1412(b)(6)(A) of the SDWA provides, with exceptions not relevant here, that "the Administrator *may*, after notice and opportunity for public comment promulgate a maximum contaminant level for the contaminant that maximizes health risk reduction benefits at a cost that is justified by the benefits." The EPA has evaluated the benefits and costs of alternative MCL values of 18 μg/L and 90 μg/L. However, based upon the available information the Administrator also finds that the benefits of an NPDWR at the alternative MCL values would not justify the resulting rule costs. The alternative MCLs would not increase net benefits, while compliance costs associated mainly with nationwide CWS monitoring requirements would remain relatively similar. Consistent with the discretion afforded the Agency by SDWA Section 1412(b)(6)(A) to decide whether or not to adjust an MCL to a level where the benefits justify the costs, the EPA is however proposing, and may finalize, the MCL of 56 μg/L notwithstanding the Agency's determination that benefits would not justify the costs.

Table XII-14: Comparison of Annual Costs and Benefits by MCL (Millions; 2017$)

MCL Value	Cost 3% Discount	Benefit 3% Discount	Cost 7% Discount	Benefit 7% Discount
UCMR 1				
90 μg/L	$9.51	$0.40 - $3.26	$10.10	$0.07 - $0.55
56 μg/L	$9.67	$0.44 - $3.57	$10.28	$0.07 - $0.60
18 μg/L	$15.95	$0.80 - $6.50	$16.88	$0.13 - $1.10
Incremental (from 90 μg/L to 56 μg/L)	$0.16	$0.04 - $0.31	$0.18	$0.0 – 0.05

Incremental (from 56 μg/L to 18 μg/L)	$6.28	$0.36 - $2.93	$6.60	$0.06 - $0.50
National				
90 μg/L	$9.51	$0.40 - $3.26	$10.10	$0.07 - $0.55
56 μg/L[1]	$9.67	$0.44 - $3.57	$10.28	$0.07 - $0.60
18 μg/L	$16.95	$0.80 - $6.56	$17.96	$0.14 - $1.11
Incremental (from 90 μg/L to 56 μg/L)	$0.16	$0.04 - $0.31	$0.18	$0.0 – 0.05
Incremental (from 56 μg/L to 18 μg/L)	$7.28	$0.36 - $2.99	$7.69	$0.07 - $0.51

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Detail may not sum to total because of independent rounding.
1. For the proposed MCL of 56 μg/L and the alternative MCL of 90 μg/L, the national estimates are the same as the estimates based on UCMR 1 data because there were no small system sample results to extrapolate to national small system estimates. At an MCL of 18 μg/L, national estimates include extrapolation for one small system entry point to national estimates based on sampling weights described above.

XIII. Uncertainty Analysis

The EPA has presented an extensive discussion of the uncertainties in the key analyses informing this proposal in the uncertainty section of the MCLG Approaches Report and the uncertainties section of the Economic Analysis document (*USEPA, 2018b; USEPA, 2019a)*. A summarized description of these uncertainties are presented below.

A. Uncertainty in the MCLG Derivation

Each input into the analysis to inform the MCLG is a decision point associated with uncertainty. There is uncertainty in different aspects of the BBDR model, ranging from structural and functional relationships to specific parameter values for early pregnancy. There are very few data available to calibrate the pharmacokinetic aspects of the model, particularly at the life stage of interest. Also, the BBDR model does not explicitly consider the effect of the presence of other goitrogens (e.g. thiocyanate, nitrate) or effects of thyroid disease states. Toxicodynamic aspects such as competitive inhibition at the NIS, depletion of iodide stores under different iodine intake levels and physiological states, and the ability of the TSH feedback loop to compensate for perturbations in thyroid function each have their own uncertain features. Additional uncertainty is introduced by linking the BBDR model estimates of maternal fT4 to altered neurodevelopment in offspring. None of the studies used to evaluate potential adverse neurodevelopmental outcomes in offspring born to hypothyroxinemic mothers was performed in the U.S. None of the studies measured perchlorate exposure. Not all the studies measured iodide levels in the study populations. The state of the science on the relationship between maternal fT4 levels and offspring neurodevelopment is constantly evolving. There are numerous indices used to assess neurodevelopmental impacts and there is some uncertainty regarding the selection of IQ as the critical endpoint for setting the MCLG.

A recently published paper evaluating the EPA's BBDR model and MCLG Approaches, reiterated the uncertainties the Agency identified in its analyses and questions the use of these quantitative tools for perchlorate in a regulatory context (Clewell et al., 2019).

B. Uncertainty in the Economic Analysis

The EPA provides discussions regarding several sources of uncertainty in the benefit and cost estimates in the Health Risk Reduction and Cost Analysis (USEPA, 2019a). Table XIII-1 provides a summary of sources of uncertainty and their potential effects on estimated costs and benefits. The following discussion addresses uncertainties specific to the benefits analysis.

Table XIII-1. Sources of Uncertainty in Economic Analysis

Description	Potential effect
Baseline Occurrence	
UCMR 1 data are more than one decade old; actual occurrence could be lower (e.g., because of contaminant cleanup) or higher (e.g., because new systems use perchlorate-contaminated source water).	± (benefits and costs will change in the same direction)
UCMR 1 data include a sample of small systems; the Stage 1 results (entry point maximums) indicate that no small systems would exceed 56 µg/L or 90 µg/L and that one small system would exceed 18 µg/L; it is possible that there are additional small systems where the baseline perchlorate is greater than the MCLs that are not captured in the national extrapolation results.	− (benefits and costs will change in the same direction)
The EPA assumed a uniform distribution of system population served across the entry points; the actual entry point service population could be greater than or less than the estimates.	± (benefits and costs will change in the same direction)
Benefits Analysis	
The health risks and risk reductions are based on maximum recorded concentration estimates and thus do not account for exposures to concentrations greater than or less than this recorded maximum.	± (benefits only)
The EPA assumed that baseline fT4 is equal to the median, which likely underestimates disease benefits as the logarithmic relationship between maternal fT4 and child IQ leads to larger relative changes in fT4, with increasing levels of perchlorate and lower levels of baseline fT4.	− (benefits only)
The EPA assumed a median TSH feedback loop strength for the exposed population does not incorporate the variability in the feedback mechanism of the body's creation of TSH in response to decreasing fT4.	± (benefits only)
The EPA used a 90th percentile water intake rate to derive the MCLG and the dose-response equations for the benefits analysis. This approach results in a protective MCLG value, but may overstate intake for the benefits analysis.	+ (benefits only)
The IQ valuation uses estimates that the EPA derived using the same approach as Salkever (1995). Results from other IQ valuation studies might result in higher or lower benefit estimates.	± (benefits only)
The benefits analysis is based on a single health endpoint and the value of the endpoint is based solely on lost earnings.	− (benefits only)

Description	Potential effect
Cost Analysis	
The EPA assumed that systems requiring treatment would incorporate a safety factor – treating to 80% of the proposed MCL or alternative MCL, which increases costs and benefits.	+ (benefits and costs will change in the same direction)
The EPA assumed that all entry points requiring treatment would implement ion exchange, which may overestimate costs if non-treatment is an option for one or more entry points or underestimate costs if site-specific conditions result in higher costs at one or more entry points.	± (costs only)
The EPA developed a monitoring schedule that assumed a uniform distribution of initial monitoring costs over three years; actual costs will vary.	± (costs only)
The EPA assumed that long-term monitoring costs would occur in the last year of the applicable three-year monitoring period or nine-year monitoring cycle; systems may conduct monitoring in an earlier year of the period or cycle.	− (costs only)
The EPA assumed that 90% of ground water systems and 40% of surface water systems obtain perchlorate monitoring waivers; the actual percentages may vary.	± (costs only)

1. A "−" symbol indicates that benefits and/or costs will tend to be underestimated. A "+" symbol indicates that benefits and/or costs will tend to be overestimated. A "±" symbol indicates an unknown direction of uncertainty, i.e., benefits and/or costs could be underestimated or overestimated.

The EPA acknowledges the uncertainty regarding the quantitative health risk reduction. In particular, the Agency assumed it could estimate risk reductions based on evidence of a quantifiable relationship between thyroid hormone changes and neurodevelopmental outcomes.

There are a number of potential benefits of reducing perchlorate in drinking water that were not quantified as part of this analysis, which may result in an underestimate of actual benefits. As described by the SAB "children exposed gestationally to maternal hypothyroxinemia (without hypothyroidism) show reduced levels of global and specific cognitive abilities, as well as increased rates of behavior problems including greater dysregulation in early infancy and attentional disorders in childhood (Man et al., 1991; Pop et al., 1999; Pop et al., 2003; Kooistra et al., 2006)" (p. 10, SAB for the U.S. EPA, 2013). The EPA's literature review identified potential relationships between maternal thyroid hormone alterations and the risk of schizophrenia, ADHD, expressive language delay, reduced school performance and increased odds of autism, among others, none of which are being currently quantified in this assessment. Other potentially omitted benefits include risks associated with effects of thyroid disorders in adults, including cardiovascular disease risk; changes in thyroid hormone levels and their relationship with total cholesterol, LDL cholesterol, and triglycerides; as well as a possible relationship between increases in TSH and risk of fatal coronary heart disease. Treating for perchlorate in drinking water could also potentially remove nitrate, which is a co-occurring contaminant and a goitrogen. These additional potential health endpoints are not monetized in this benefits analysis. The assumptions used to account for the previously mentioned variability of the BBDR model inputs and uncertainty surrounding the relationship between maternal fT4 and child IQ discussed above may result in an overestimate of the monetized benefits. Because IQ is a surrogate for broad range of potential neurodevelopmental risks, it is unclear whether the analysis as a whole over- or under-estimates the monetized benefits of a reduction of perchlorate in drinking water.

XIV. Request for Comment on Proposed Rule

While all comments relevant to the national primary drinking water regulation for perchlorate proposed today will be considered by the EPA, comments on the following issues will be especially helpful to the EPA in developing a final rule. The EPA specifically requests comment on the following topics.

- The adequacy and uncertainties of the BBDR model developed by the EPA to predict thyroid hormone level changes caused by perchlorate exposure to pregnant women with low iodide intake, including the model and model parameters and assumptions (Section III and Approaches Report).

- The adequacy and uncertainties of the EPA's review and application of the epidemiologic literature to quantify the relationship between thyroid hormone changes in pregnant women and neurodevelopmental effects including the assumptions, the selection of the approach used, and the study used (Section III and Approaches Report).
- The adequacy and uncertainties of the methodology to derive the MCLG including points of departure, assumptions, uncertainty factor, and relative source contribution (Section III and Technical Support Document: Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water).
- The proposed MCLG and MCL of 56 μg/L as well as the alternative MCLG and MCL values of 18 μg/L and of 90 μg/L.
- The feasibility of the proposed MCL of 56 μg/L as well as the feasibility of the alternative MCLs of 18 μg/L and 90 μg/L.
- The adequacy of the underlying assumptions and analysis of occurrence (Section VI).
- The costs and availability of Treatment Technologies (Section X).
- The adequacy of the underlying estimates, assumptions and analysis used to estimate costs and describe unquantified costs including the estimates of monitoring frequency, likelihood of systems receiving a monitoring waiver, the administrative labor rate and the operator labor rate. (Section XII and the Health Risk Reduction Cost Analysis).

- The adequacy of the underlying estimates, assumptions and analysis used to estimate benefits and describe unquantified benefits (Section XII and the Health Risk Reduction Cost Analysis).
- Potential implementation challenges associated with the proposed perchlorate regulation that the EPA should consider, specifically for small systems.
- The Administrator's finding in accordance with Section 1412(b)(4)(C) of the SDWA that the benefits of the proposed 56 μg/L MCL for perchlorate do not justify the costs, and the information that supports that determination as described in Section XII of this notice.
- The Administrator's proposal to, consistent with the discretion afforded him by SDWA Section 1412(b)(6)(A), adopt an MCL of 56 μg/L notwithstanding the Agency's SDWA Section 1412(b)(4)(C) determination that the benefits of the MCL would not justify its costs.
- The Agency's conclusion that no alternative MCL, including the alternative MCL values of 18 μg/L and 90 μg/L discussed above, would "maximize health risk reduction benefits at a cost that is justified by the benefits" and the information and analytical approaches used to arrive at that conclusion. The EPA is especially interested in comments suggesting other approaches to deriving an MCL for which the benefits justify the costs.

XV. Request for Comment on Potential Regulatory Determination Withdrawal

The EPA is soliciting comments on withdrawing the 2011 Regulatory Determination (see Section II-C, Regulatory History) based on several factors. First, the findings, described in the occurrence section (section VI) and in the updated health effects assessment (Section III), suggest that perchlorate does not occur in public water systems with a frequency and at levels of public health concern[17] and suggest that the regulation of perchlorate does not present a meaningful opportunity for health risk reduction for persons served by public water systems. The proposed regulation would require over sixty thousand public water systems to monitor for perchlorate, but the available data indicates that very few would find it at levels of public health concern. Specifically, perchlorate occurrence information suggests that at an MCL of 56 µg/L only 2 systems (0.004% of all water systems in the U.S.) would exceed the regulatory threshold. Even at an MCL of 18 µg/L, there would only be 15 systems (0.03% of all water systems in the U.S.) that would exceed the regulatory threshold. Only one system would exceed the alternative MCL of 90 µg/L.

The EPA notes that in 2008, the EPA stated in its preliminary regulatory determination that perchlorate did not occur with a frequency and at levels of public health concern in public water systems based upon the health effects and occurrence information available at that time, which indicated that 0.8% of public water system had perchlorate at levels exceeding the HRL of 15 µg/L. The EPA also stated that there was not a meaningful opportunity for a NPDWR to reduce health risks based upon the estimates at that time that 0.9 million people had perchlorate levels above the HRL.

The EPA further notes that the Agency has previously determined CCL1 and CCL2 contaminants did not occur with frequency at levels of public health concern when the percentage of water systems exceeding the HRL were greater than the frequency of perchlorate

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[17] As shown in Section VI of this notice there is infrequent occurrence of perchlorate at either 56 µg/L, 18 µg/L or 90 µg/L, which are the possible levels expected to cause adverse human health effects.

occurrence level at the proposed MCL (0.004% of all water systems in the U.S.). For example, in 2003 the EPA determined that aldrin did not occur with a frequency and at levels of public health concern based upon data that showed 0.2% of water systems had aldrin at levels greater than the HRL. The EPA also concluded that there was not a meaningful opportunity for health risk reduction for persons served through a drinking water regulation based on this occurrence data and the estimate that these systems above the HRL served approximately 1 million people (USEPA, 2003). In 2008 the EPA determined that DCPA Mono- and Di-Acid degradates did not occur with a frequency and at levels of public health concern based on data that showed 0.03% of water systems exceeded the HRL. The EPA also included that there was not a meaningful opportunity for health risk reduction through a drinking water regulation based on this occurrence data and the estimate that these systems above the HRL served approximately 100,000 people (USEPA, 2008e).

SDWA Section 1412(b)(1)(A)(iii) states that the determination regarding the meaningful opportunity is "in the sole judgement of the Administrator" and therefore there may be other factors that contribute to this determination for any given contaminant.

If, after consideration of public comment, the EPA withdraws the perchlorate regulatory determination, there will be no NPDWR for perchlorate, although the EPA can re-list perchlorate on the CCL and proceed to regulation in the future if the occurrence or risk information changes. As with other unregulated contaminants, the EPA could address the limited instances of elevated levels of perchlorate by working with the states or using its SDWA Section 1431 imminent and substantial endangerment or Section 1412(b)(1)(f) health assessment authorities, as appropriate.

The EPA also requests comments on what guidance it could provide the public if the regulatory determination for perchlorate is withdrawn.

XVI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action since it raises novel legal or policy issues. It was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

The EPA evaluated the potential costs to States and utilities and the potential benefits of the proposed rule. This analysis, *Health Risk Reduction Cost Analysis of the Proposed Perchlorate Rule (USEPA, 2019a)* is available in the docket and is summarized in section XI.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Cost

This action is expected to be an Executive Order 13771 regulatory action. Details on the estimated costs of this proposed rule can be found in the EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*. The information collection requirements are not enforceable until OMB approves them.

The monitoring information collected as a result of this rule will allow the States and the EPA to evaluate compliance with the rule. For the first 3-year period following rule promulgation, the major information requirements concern primacy agency activities to implement the rule including adopting the NPDWR into state regulations, providing training to state and PWS employees, updating their monitoring data systems, and reviewing system monitoring data and waiver requests. Compliance actions for drinking water systems (including monitoring, administration, and treatment costs) would not begin until after Year 3 due to the proposed effective date of this rule.

The estimate of annual average burden hours for the proposed rule during the first three years following promulgation is 48,539 hours. The annual average cost estimate is $7.4 million for labor. The burden hours per response is 2,648 hours and the cost per response is $134,159. The frequency of response (average responses per respondent) is 1 for primacy agencies, annually (for upfront administrative activities to implement the rule). The estimated number of likely respondents is 55 over the three-year period (for an average of 18.3 each year).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, to the EPA at the public docket established for this rule, which includes the ICR, Docket ID No. **EPA-HQ-OW-2018-0780**. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to OIRA_submission@omb.eop.gov, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than **[insert date 30 days after publication in the *Federal Register*]**. The EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The Agency has determined that the proposed MCL of 56 μg/L will not result in annual costs that exceed one percent of revenue for small systems affected by the proposed rule.

The small entities subject to the requirements of this action are public water systems serving 10,000 or fewer persons. This is the threshold specified by Congress in the 1996

Amendments to the Safe Drinking Water Act for small system flexibility provisions. In accordance with the RFA requirements, the EPA proposed using this alternative definition in the Federal Register, (63 FR 7620, February 13, 1998), requested public comment, consulted with the Small Business Administration (SBA), and expressed its intention to use the alternative definition for all future drinking water regulations in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). As stated in that final rule, the alternative definition is applied to this proposed regulation.

The proposed rule contains provisions that would affect 58,325 CWS and NTNCWS serving 10,000 or fewer people. In order to meet the proposed rule requirements, all of these systems will need to conduct perchlorate monitoring. At the proposed MCL of 56 μg/L, the UCMR 1 monitoring data indicate that no small systems would be required to incur costs to reduce the levels of perchlorate in drinking water, therefore, all small PWSs will incur monitoring costs only. Impacts on small entities are described in more detail in Chapter 7 of the Health Risk Reduction Cost Analysis of the Proposed Perchlorate Rule (USEPA, 2019a). Table XII-1 and Table XII-2 show the annual compliance costs of the proposed rule on the small entities by system size for public and private systems, respectively. Based on a comparison of annual costs with annual revenue estimates, the EPA has determined that no small systems will experience an impact of one percent or greater of average annual revenues (USEPA 2019a).

Table XII-1: Annualized Monitoring and Administrative Costs as a Percentage of Average Annual Revenue for Small Public CWSs by Size Category

Size Category	Average Annual Revenues[a]	3% Discount[b]	7% Discount[b]
Population served <100	$224,248	$88 (0.04%)	$94 (0.04%)
Population served 101-500	$197,315	$88 (0.04%)	$94 (0.05%)

Population served 501-3,300	$202,382	$88 (0.04%)	$94 (0.05%)
Population served 3,301-10,000	$1,092,187	$88 (0.01%)	$94 (0.01%)

Source: Perchlorate Benefit-Cost Analysis Spreadsheet available in the proposed rule docket (EPA-HQ-OW-2018-0780)

a. Based on the CWSS [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ZkgC4dzL","properties":{"formattedCitation":"(USEPA, 2009c Table 65)","plainCitation":"(USEPA, 2009c Table 65)","noteIndex":0},"citationItems":[{"id":924,"uris":["http://zotero.org/groups/945096/items/DZNAAV6M"],"uri":["http://zotero.org/groups/945096/items/DZNAAV6M"],"itemData":{"id":924,"type":"article","title":"2006 Community Water System Survey - Volume II: Detailed Tables and Survey Methodology","URL":"https://www.epa.gov/dwstandardsregulations/community-water-system-survey","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2009",5]]},"accessed":{"date-parts":[["2018",8,16]]}},"suffix":"Table 65"}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] and updated to 2017$ based on the chained consumer price index for fuels and utilities in U.S. city average, all urban consumers [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"rkwEpGYT","properties":{"formattedCitation":"(Bureau of Labor Statistics (BLS), 2018a)","plainCitation":"(Bureau of Labor Statistics (BLS), 2018a)","noteIndex":0},"citationItems":[{"id":984,"uris":["http://zotero.org/groups/945096/items/E3I7HRK8"],"uri":["http://zotero.org/groups/945096/items/E3I7HRK8"],"itemData":{"id":984,"type":"article","title":"Chained consumer price index for fuels and utilities in U.S. city average, all urban consumers, 2000 to 2018","author":[{"literal":"Bureau of Labor Statistics (BLS)"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Revenues include all sources of revenue including water revenue, non-water revenue, and municipal transfers to water systems.

b. Total annual monitoring and administrative costs for PWSs are approximately $6.6 million to $7.1 million annually (Exhibit 5 5), with $5.1 million to $5.5 million accruing to small PWSs. Based on 58,325 small systems, this yields an average annual per-system cost of $88 (3% discount rate) to $94 (7% discount rate).

Table XII-2: Annualized Monitoring and Administrative Costs as a Percentage of Average Annual Revenue for Small Private CWSs by Size Category

Size Category	Average Annual Revenues[a]	3% Discount[b]	7% Discount[b]
Population served <100	$139,911	$88 (0.06%)	$94 (0.07%)
Population served 101-500	$351,974	$88 (0.03%)	$94 (0.03%)
Population served 501-3,300	$254,706	$88 (0.03%)	$94 (0.03%)
Population served 3,301-10,000	$951,692	$88 (0.01%)	$94 (0.01%)

Source: Perchlorate Benefit-Cost Analysis Spreadsheet available in the proposed rule docket (EPA-HQ-OW-2018-0780)

a. Based on the CWSS [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ZkgC4dzL","properties":{"formattedCitation":"(USEPA, 2009c Table 65)","plainCitation":"(USEPA, 2009c Table 65)","noteIndex":0},"citationItems":[{"id":924,"uris":["http://zotero.org/groups/945096/items/DZNAAV6M"],"uri":["http://zotero.org/groups/945096/items/DZNAAV6M"],"itemData":{"id":924,"type":"article","title":"2006 Community Water System Survey - Volume II: Detailed Tables and Survey Methodology","URL":"https://www.epa.gov/dwstandardsregulations/community-water-system-survey","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2009",5]]},"accessed":{"date-parts":[["2018",8,16]]}},"suffix":"Table 65"}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] and updated to 2017$ based on the chained consumer price index for fuels and utilities in U.S. city average, all urban consumers [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"rkwEpGYT","properties":{"formattedCitation":"(Bureau of Labor Statistics (BLS), 2018a)","plainCitation":"(Bureau of Labor Statistics (BLS), 2018a)","noteIndex":0},"citationItems":[{"id":984,"uris":["http://zotero.org/groups/945096/items/E3I7HRK8"],"uri":["http://zotero.org/groups/945096/items/E3I7HRK8"],"itemData":{"id":984,"type":"article","title":"Chained consumer price index for fuels and utilities in U.S. city average, all urban consumers, 2000 to 2018","author":[{"literal":"Bureau of Labor Statistics (BLS)"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Revenues include all sources of revenue including water revenue and non-water revenue.
b. Total annual monitoring and administrative costs for PWSs are approximately $6.6 million to $7.1 million annually (Exhibit 5 5), with $5.1 million to $5.5 million accruing to small PWSs. Based on 58,325 small systems, this yields an average annual per-system cost of $88 (3% discount rate) to $94 (7% discount rate).

E. Unfunded Mandates Reform Act

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538. The action imposes minimal enforceable duty on any state, local or tribal governments or the private sector

Based on the cost estimates detailed in Section XI, the EPA determined that compliance costs in any given year would be below the threshold set in UMRA, with maximum single-year costs of approximately $10.2 million. The EPA has determined that this rule contains a federal mandate that would not result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects of greater than $25 million on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Annual costs are estimated to range from $9.6 million at a 3 percent discount rate to $10.2 million using a 7 percent, with $6.5 million to $7.0 million annually accruing to public entities. The EPA has concluded that this proposed rule may be of interest because it may impose direct compliance costs on State or local governments, and the federal government will not provide the funds necessary to pay those costs.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

The EPA has concluded that this proposed rule may have Tribal implications, because it may impose direct compliance costs on Tribal governments, and the federal government would not provide the funds necessary to pay those costs. The EPA has identified 768 water systems with 1,167 entry points under Native American ownership that may be subject to the proposed rule. They would bear an estimated total annualized cost of $74,100 at a 3 percent discount rate ($79,625 at 7 percent) to implement this rule as proposed, with all costs attributable to monitoring and administrative costs. Estimated average annualized cost per system ranges from $96 at a 3 percent discount rate to $104 at a 7 percent discount rate.

Accordingly, the EPA provides the following Tribal summary impact statement as required by section 5(b) of Executive Order 13175. The EPA consulted with representatives of Tribal officials early in the process of developing this proposed regulation to permit them to have meaningful and timely input into its development. The EPA conducted consultation with Indian Tribes which included a webinar with interested tribes on February 28, 2012, to request input and provide rulemaking information to interested parties. A meeting summary report is available on the docket for public inspection (USEPA 2012a). The EPA notes that 751 of the 768 Tribal systems identified by the Agency as subject to the proposed rule are small systems that are expected to incur only monitoring costs. Due to the health risks associated with perchlorate, capital expenditures needed for compliance with the rule would be eligible for federal funding sources, specifically the Drinking Water State Revolving Fund. In the spirit of Executive Order 13175, and consistent with the EPA policy to promote communications between the EPA and Tribal governments, the EPA specifically solicits additional comment on this proposed rule from Tribal officials.

H. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866; however, the environmental health risk addressed by this action may have a disproportionate effect on children. Accordingly, the EPA evaluated the environmental health or safety effects of perchlorate on children. The results of this evaluation are contained in the Health Effects Technical Support Document (USEPA 2018a) and described in section III of this preamble. The EPA has evaluated the risk associated with perchlorate in drinking water for the sensitive subpopulation – offspring of pregnant women exposed to perchlorate during the first trimester – and established a proposed MCLG that is protective of this subpopulation as well as other children. The EPA also estimated the health risk reduction of the proposed and alternative MCLs. This analysis is described in the Health Risk Reduction and Cost Analysis for the proposed rule (USEPA 2019a) and is summarized in section XI of this preamble. Copies of the Health Effects Technical Support Document and Economic Analysis and supporting information are available in the public docket for today's proposal.

I. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This determination is based on the following analysis.

The first consideration is whether the proposed rule would adversely affect the supply of energy. The proposed rule does not regulate power generation, either directly or indirectly. The public and private water systems that the proposed rule regulates do not generate power. Further, the cost increases borne by customers of water utilities as a result of the proposed rule are a low percentage of the total cost of water, except for a few water systems that might install treatment technologies and would likely spread that cost over their customer base. In sum, the proposed rule does not regulate the supply of energy, does not generally regulate the utilities that supply energy, and is unlikely to affect significantly the customer base of energy suppliers. Thus, the proposed rule would not translate into adverse effects on the supply of energy.

The second consideration is whether the proposed rule would adversely affect the distribution of energy. The proposed rule does not regulate any aspect of energy distribution. The water systems that are regulated by the proposed rule already have electrical service. At the proposed MCL, one entry point at one system may require incremental power to operate new treatment processes. The increase in peak electricity demand at water utilities is negligible. Therefore, the EPA estimates that the existing connections are adequate and that the proposed rule has no discernable adverse effect on energy distribution.

The third consideration is whether the proposed rule would adversely affect the use of energy. Because only one system is expected to add treatment technologies that use electrical power, this potential impact on sector demand or overall national demand for power is negligible.

Based on its analysis of these considerations, the EPA has concluded that proposed rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

J. National Technology Transfer and Advancement Act of 1995

The proposed rule could involve voluntary consensus standards in that it would require monitoring for Perchlorate. The EPA proposed five analytical methods for the identification and quantification of perchlorate in drinking water. The EPA methods 314.0, 314.1, 314.2, 331.0, and 332.0 incorporate quality control criteria which allow accurate quantitation of perchlorate. Additional information about the analytical methods is available in section VII of this notice.

The EPA's monitoring and sampling protocols generally include voluntary consensus standards developed by agencies such as ASTM International, Standard Methods and other such bodies wherever the EPA deems these methodologies appropriate for compliance monitoring. The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA has determined that this proposed rule would not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it would increase the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

The public is invited to comment on this aspect of the proposed rulemaking and, specifically, to recommend additional methods to address Environmental Justice concerns from establishing a drinking water rule for perchlorate in drinking water.

XVII. Consultations with the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with sections 1412(d) and 1412(e) of the Safe Drinking Water Act (SDWA), the Agency consulted with the National Drinking Water Advisory Council (NDWAC or the Council); the Secretary of Health and Human Services; and with the EPA Science Advisory Board. The Agency consulted with NDWAC during the Council's October 4-5, 2012 meeting. A summary of the NDWAC recommendations is available in the National Drinking

Water Advisory Council, Fall 2012 Meeting Summary Report (NDWAC, 2012b) and the docket for this proposed rule. The EPA carefully considered NDWAC recommendations during the development of a proposed drinking water rule for perchlorate.

On May 29, 2012, the EPA sought guidance from the EPA Science Advisory Board (SAB) on how best to consider and interpret life stage information, epidemiological and biomonitoring data since the publication of the National Research Council 2005 report, the Agency's physiologically-based pharmacokinetic (PBPK) analyses, and the totality of perchlorate health information to derive a Maximum Contaminant Level Goal (MCLG) for perchlorate (USEPA, 2012; NRC, 2005). On May 29, 2013, the EPA received significant input from SAB, summarized in the report, SAB Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate (USEPA, 2013a).

On July 15, 2013, the EPA responded by stating that the Agency would consider all the recommendations from the SAB, as it continued working on the development of the rulemaking process for perchlorate (USEPA 2013b). To address SAB recommendations, the EPA collaborated with Food and Drug Administration (FDA) scientists to develop PBPK/pharmacodynamic (PD), or biologically based dose-response (BBDR), models that incorporate all available health related information on perchlorate to predict changes in thyroid hormones in sensitive life stages exposed to different dietary iodide and perchlorate levels (USEPA 2017). As recommended by SAB, the EPA developed these models based upon perchlorate's mode of action (i.e., iodide uptake inhibition by the thyroid) (USEPA 2013a).

Additional details are in section III.C. of this notice and in the Health Effects of Perchlorate support document located in the docket for this proposed rule.

In accordance with SAB recommendations, the EPA developed a two-stage approach to integrate BBDR model results with data on neurodevelopmental outcomes from epidemiological studies, this approach allowed the Agency to link maternal thyroid hormones levels as a result of low iodine intake and perchlorate exposure, to derive an MCLG that directly addresses the most sensitive life stage (USEPA 2013a).

On March 25, 2019, the EPA consulted with the Department of Health and Human Services (HHS). The EPA provided information to HHS officials on the draft proposed perchlorate regulation and considered HHS input as part of the interagency review described in section XVII.A.

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List of Subjects in 40 CFR Parts 141, and 142

Administrative practice and procedure, Chemicals, Indians-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated:____________________

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Andrew R. Wheeler,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency proposes to amend 40 CFR part 141 and 40 CFR part 142 as follows:

PART 141 - NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for part 141 continues to read as follows:

   Authority: 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9, and 300j-11.

2. Amend § 141.6 by revising paragraph (a) and adding paragraph (l).

3. Amend § 141.23 by:

   a. Revising the title in the table in paragraph (a)(4)(i);

   b. Adding "Perchlorate" in alphabetical order, in the table in paragraph (a)(4)(i);

   c. Adding "perchlorate" in paragraph (a)(5);

   d. Adding "perchlorate" in alphabetical order, in paragraph (c);

   e. Adding paragraph (c)(10);

   f. Adding "perchlorate" in alphabetical order, in paragraph (f)(1);

   g. Adding "perchlorate" in alphabetical order, to the first sentence in paragraph (i)(1);

   h. Adding "perchlorate" in alphabetical order, to the first sentence in paragraph (i)(2);

   i. Revising paragraph (i)(3);

   j. Revising paragraph (k)(1);

   k. Adding "perchlorate" in alphabetical order, to the second sentence in paragraph (k)(1);

l. Adding an entry for "21. Perchlorate" in alphabetical order, in the table in paragraph (k)(1);

m. Adding "perchlorate" in alphabetical order, to paragraph (k)(2);

n. Adding "Perchlorate" in alphabetical order, in the table in paragraph (k)(2);

o. Adding "perchlorate" in alphabetical order, to the third sentence in paragraph (k)(3); and

p. Adding an entry for "Perchlorate" in alphabetical order, in the table in paragraph (k)(3)(ii).

4. Amend § 141.51 by adding an entry for "Perchlorate" in alphabetical order, in the table in paragraph (b).

5. Amend § 141.60 by adding paragraph (b)(5).

6. Amend § 141.62 by:

a. Adding an entry (17) for "Perchlorate" in paragraph (b);

b. Adding an entry for "Perchlorate" in alphabetical order, to the table in paragraph (c);

c. Adding an entry "14 = Biological Treatment" in the table Key to BATs in paragraph (c);

d. Adding paragraph (e); and

e. Adding a table in paragraph (e).

7. Amend Appendix A to Subpart O of Part 141 by adding an entry for "Perchlorate" in the table entitled "APPENDIX A TO SUBPART O OF PART 141 – REGULATED CONTAMINANTS."

8. Amend Appendix A to Subpart Q of Part 141 by adding an entry for "Perchlorate" in the table entitled "APPENDIX A TO SUBPART Q OF PART 141 - NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTIFICATION."
9. Amend Appendix B to Subpart Q of Part 141 by adding an entry for "Perchlorate" in the table entitled "APPENDIX B TO SUBPART Q OF PART 141 – STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION."

The revisions and additions read as follows:

Subpart A—General

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§ 141.6 Effective Dates.

(a) Except as provided in paragraphs (b) through (l) of this section the regulations set forth in this part shall take effect on June 24, 1977.

*****

(l) The regulations contained in the revisions to §§141.23(a)(4)(i), 141.23(a)(5), 141.23(c),141.23(f)(1), 141.23(i)(1)-(2), 141.23(k)(1)-(3), 141.23(k)(3)(ii), 141.51(b), 141.60(b)(5), 141.62(b), 141.62(c), 141.62(e), Appendix A to Subpart O and Appendix A and B to Subpart Q are effective for the purposes of compliance on [insert date].

Subpart C—Monitoring and Analytical Requirements

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§141.23 Inorganic chemical sampling and analytical requirements.

*****

(a)***

(4)***

(i)***

DETECTION LIMITS FOR INORGANIC CONTAMINANTS (COMPOSITED SAMPLES)

Contaminant	MCL (mg/l)	Methodology	Detection limit (mg/l)
*******	*******	*******	*******
Perchlorate	0.056	Ion Chromatography	0.00053
		Inline Column Concentration/Matrix Elimination Ion Chromatography with Suppressed Conductivity Detection	0.00003
		Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection	0.000012-0.000018
		Liquid Chromatography Electrospray Ionization Mass Spectrometry	0.000005 (Tandem Mass Spectrometry [MS/MS]) 0.000008 (Selected Ion Monitoring [SIM])
		Ion Chromatography with Suppressed Conductivity and Electrospray Ionization Mass Spectrometry	0.00002
*******	*******	*******	*******

*****

*****

(c)***

(10) Community water systems and non-transient non-community water systems must conduct initial monitoring for perchlorate as follows:

(i) Community water systems serving greater than 10,000 persons without acceptable historic data, as defined below, must collect four consecutive quarterly samples at all sampling points between January 1, 2023, and December 31, 2025.

(ii) Community water systems serving 10,000 or fewer persons and non-transient non-community water systems without acceptable historic data, as defined below, must collect four consecutive quarterly samples at all sampling points between January 1, 2026, and December 31, 2028.

(iii) Grandfathering of data: States may allow historical monitoring data collected at a sampling point to satisfy the initial monitoring requirements for that sampling point, for the following situations.

(A) To satisfy initial monitoring requirements, community water systems serving greater than 10,000 persons having only one entry point to the distribution system may use the monitoring data from the compliance monitoring period between January 1, 2020, and December 31, 2022. Community water systems serving 10,000 or fewer persons and non-transient non-community water systems having only one entry point to the distribution system may use the monitoring data from the compliance monitoring period between January 1, 2023, and December 31, 2025.

(B) To satisfy initial monitoring requirements, a system with multiple entry points and having appropriate historical monitoring data for each entry point to the distribution system may use the monitoring data from the compliance monitoring period that began between January 1, 2020, and December 31, 2022, for community water systems serving greater than 10,000 persons and between January 1, 2023, and December 31, 2025, for community water systems serving 10,000 or fewer persons and for non-transient non-community water systems.

(C) To satisfy initial monitoring requirements, a system with appropriate historical data for a representative point in the distribution system may use the monitoring data from the compliance monitoring period between January 1, 2020, and December 31, 2022, for community water systems serving greater than 10,000 persons and between January 1, 2023, and December 31, 2025, for community water systems serving 10,000 or fewer persons and for non-transient non-community water systems, provided that the State finds that the historical data satisfactorily demonstrate that each entry point to the distribution system is expected to be in compliance based upon the historical data and reasonable assumptions about the variability of contaminant levels between entry points. The State must make a written finding indicating how the data conforms to these requirements.

(iv) The State may waive the final two quarters of initial monitoring for perchlorate for a sampling point if the results of the samples from the previous two quarters are below the detection limit.

*****

(i)***

(3) Compliance with the maximum contaminant level for nitrate, nitrite and perchlorate is determined based on one sample if the levels of these contaminants are below the MCLs. If the level of perchlorate exceeds the MCL in the initial sample, a confirmation sample is required in accordance with paragraph 141.23(f)(1) and compliance shall be based on the average of the initial and confirmation sample. If the levels of nitrate and/or nitrite exceed the MCLs in the initial sample, a confirmation sample is required in accordance with paragraph 141.23(f)(2) and compliance shall be based on the average of the initial and confirmation sample.

*****

(k)***

(1) Analysis for the following contaminants shall be conducted in accordance with the methods in the following table, or the alternative methods listed in Appendix A to subpart C of this part, or their equivalent as determined by the EPA.

*****

Contaminant	**Methodology[13]**	**EPA**	**ASTM[3]**	**SM[4] (18th, 19th ed.)**	**SM[4] (20th ed.)**	**SM Online[22]**	**Other**
******	******	*******	*******	*******	*******	*******	*******
Perchlorate	Ion Chromatography Inline Column Concentration/Matrix Elimination Ion Chromatography with Suppressed	314.0 314.1					

	Conductivity Detection Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection Liquid Chromatography Electrospray Ionization Mass Spectrometry Ion Chromatography with Suppressed Conductivity and Electrospray Ionization Mass Spectrometry	 314.2 331.0 332.0					
******	*******	*******	*******	*******	*******	*******	*******

*****

[3]Annual Book of ASTM Standards, ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428, http://www.astm.org.; Annual Book of ASTM Standards 1994, Vols. 11.01 and 11.02; Annual Book of ASTM Standards 1996, Vols. 11.01 and 11.02; Annual Book of ASTM Standards 1999, Vols. 11.01 and 11.02; Annual Book of ASTM Standards 2003, Vols. 11.01 and 11.02.

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[4]Standard Methods for the Examination of Water and Wastewater, American Public Health Association, 800 I Street NW., Washington, DC 20001-3710; Standard Methods

for the Examination of Water and Wastewater, 18th edition (1992); Standard Methods for the Examination of Water and Wastewater, 19th edition (1995); Standard Methods for the Examination of Water and Wastewater, 20th edition (1998).The following methods from this edition cannot be used: 3111 B, 3111 D, 3113 B, and 3114 B.

*****

[13]Because MDLs reported in EPA Methods 200.7 and 200.9 were determined using a 2x preconcentration step during sample digestion, MDLs determined when samples are analyzed by direct analysis (i.e., no sample digestion) will be higher. For direct analysis of cadmium and arsenic by Method 200.7, and arsenic by Method 3120 B, sample preconcentration using pneumatic nebulization may be required to achieve lower detection limits. Preconcentration may also be required for direct analysis of antimony, lead, and thallium by Method 200.9; antimony and lead by Method 3113 B; and lead by Method D3559-90D, unless multiple in-furnace depositions are made.

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[22]Standard Methods Online, American Public Health Association, 800 I Street NW., Washington, DC 20001, available at http://www.standardmethods.org. The year in which each method was approved by the Standard Methods Committee is designated by the last two digits in the method number. The methods listed are the only online versions that may be used.

*****

(2)***

Contaminant	Preservative[1]	Container[2]	Time[3]
*******	*******	*******	*******
Perchlorate[7]	4 °C	P or G	28 days
*******	*******	*******	******

[1]For cyanide determinations samples must be adjusted with sodium hydroxide to pH 12 at the time off collection. When chilling is indicated the sample must be shipped and stored at 4 °C or less. Acidification of nitrate or metals samples may be with a concentrated acid or a dilute (50% by volume) solution of the applicable concentrated acid. Acidification of samples for metals analysis is encouraged and allowed at the laboratory rather than at the time of sampling provided the shipping time and other instructions in Section 8.3 of EPA Methods 200.7 or 200.8 or 200.9 are followed.

[2]P = plastic, hard or soft; G = glass, hard or soft.

[3]In all cases samples should be analyzed as soon after collection as possible. Follow additional (if any) information on preservation, containers or holding times that is specified in method.

*****

[7] Sample collection for perchlorate shall be conducted following the requirements specified in the approved methods in 141.23(k)(1) or the alternative methods listed in appendix A of subpart C of this part, or their equivalent as determined by the EPA.

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(3)***

(ii)***

Contaminant	Acceptance limit
*******	*******
Perchlorate	±20% at ≥0.004 mg/L
*******	*******

*****

Subpart F—Maximum Contaminant Level Goals and Maximum Residual Disinfectant Level Goals

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§141.51 Maximum contaminant level goals for inorganic contaminants.

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(b)***

Contaminant	MCLG (mg/l)
*******	*******
Perchlorate	0.056
*******	*******

*****

Subpart G—National Primary Drinking Water Regulations: Maximum Contaminant Levels and Maximum Residual Disinfectant Levels

§141.60 Effective dates.

(a) ***

(5) The effective date for §141.62(b)(17) is [insert date].

§141.62 Maximum contaminant levels for inorganic contaminants.

*****

(b)***

Contaminant	MCL (mg/l)
*******	*******
(17) Perchlorate	0.056

(c)***

BAT FOR INORGANIC COMPOUNDS LISTED IN SECTION 141.62(b)

Chemical Name	BAT(s)
*******	********
Perchlorate	5, 7, 14
*******	*******

*****

Key to BATs in Table

*****

5 = Ion Exchange

*****

7 = Reverse Osmosis

*****

14 = Biological Treatment

*****

(e)The Administrator, pursuant to section 1412 of the Act, hereby identified in the following table the affordable technology, treatment technique, or other means available to systems serving 10,000 persons or fewer for achieving compliance with the maximum contaminant level for perchlorate:

SMALL SYSTEM COMPLIANCE TECHNOLOGIES (SSCTs) FOR PERCHLORATE

Small system compliance technology	**Affordability for listed small system categories**
Ion exchange	All size categories.
Reverse osmosis (point of use)	All size categories

Subpart O – Consumer Confidence Reports

*****

APPENDIX A TO SUBPART O OF 141 – REGUATED CONTAMINANTS

Contaminant (units)	**Traditional MCL in mg/L**	**To convert for CCR, multiply by**	**MCL in CCR units**	**MCLG**	**Major sources in drinking water**	**Health effects language**
********	*******	*******	*******	*******	*******	*******
Inorganic contaminants						
********	********	********	*******	*******	*******	*******

Perchlorate	0.056	1000	56	56	Perchlorate is commonly used in solid rocket propellants, munitions, fireworks, airbag initiators for vehicles, matches and signal flares. Perchlorate may occur naturally, particularly in arid regions such as the southwestern United States and is found as a natural impurity in nitrate salts used to produce nitrate fertilizers, explosives and other products.	Offspring of pregnant women and infants who drink water containing perchlorate in excess of the MCL could experience delays in their physical or mental development.
*******	*******	*******	*******	*******	*******	*******

Subpart Q – Public Notification of Drinking Water Violations

*****

APPENDIX A TO SUBPART Q OF PART 141 – NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE[1]

Contaminant	MCL/MRDL/TT violations[2]		Monitoring & testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
*******				
B. Inorganic Chemicals (IOCs)				
*******				

14. Perchlorate	1	141.62(b)	3	141.23(a), (c), 141.23(f)(1)
*******				

[1] Violations and other situations not listed in this table (e.g., failure to prepare Consumer Confidence Reports), do not require notice, unless otherwise determined by the primacy agency. Primacy agencies may, at their option, also require a more stringent public notice tier (e.g., Tier 1 instead of Tier or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under 141.202(a) and 141.203(a).

[2] MCL-Maximum contaminant level, MDRL-Maximum residual disinfectant level, TT-treatment technique

*****

APPENDIX B TO SUBPART Q OF PART 141 – STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
*******			
C. Inorganic Chemicals (IOCs)			
*******	*******	*******	*******
21. Perchlorate	0.056	0.056	Offspring of pregnant women and infants who drink water containing perchlorate in excess of the MCL could experience delays in their physical or mental development.
*******	*******	*******	*******

[1] MCLG – Maximum contaminant level goal

[2] MCL – Maximum contaminant level

PART 142 - NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

1. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9, and 300j-11.

2. In § 142.62:

a. Add an entry for "Perchlorate" to the table in paragraph (b); and

b. Add entry "14 = Biological Treatment" in the table's *Key to BATs* in paragraph (b).

Subpart G – Identification of Best Technology, Treatment Techniques or Other Means Generally Available.

*****

§142.62 Variances and exemptions from the maximum contaminant levels for organic and inorganic chemicals.

*****

(b)***

BAT FOR INORGANIC COMPOUNDS LISTED IN §141.62(b)

Chemical Name	BAT(s)
*******	********
Perchlorate	5, 7, 14

*******	*******

*****

Key to BATs in Table

*****

5 = Ion Exchange

*****

7 = Reverse Osmosis

*****

14 = Biological Treatment

*****

[FILENAME * MERGEFORMAT]

6560-50-P

ENVI RONMENTAL PROTECTION AGENCY

40 CFR Parts 141, and 142

[EPA-HQ-OW-2018-0780; FRL-XXXX-XX-OW]

RIN 2040-AF28

National Primary Drinking Water Regulations: Proposed Perchlorate Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule, request for public comment.

SUMMARY: The Environmental Protection Agency (EPA) is proposing a drinking water regulation for perchlorate and a health-based Maximum Contaminant Level Goal (MCLG) in accordance with the Safe Drinking Water Act (SDWA). The EPA is proposing to set both the enforceable Maximum Contaminant Level (MCL) for the perchlorate regulation and the perchlorate MCLG at 0.056 mg/L (56 μg/L). The EPA is proposing requirements for water systems to conduct monitoring and reporting for perchlorate and to provide information about perchlorate to their consumers through public notification and consumer confidence reports. This proposal includes requirements for primacy agencies that implement the public water system supervision program under the SDWA. This proposal also includes a list of treatment technologies that would enable water systems to comply with the MCL, including affordable compliance technologies for small systems serving 10,000 persons or less.

In addition to the proposed regulation, the EPA is requesting comment on three alternatives: 1) whether the MCL and MCLG for perchlorate should be set at 0.018 mg/L (18 µg/L), 2) whether the MCL and MCLG for perchlorate should be set at 0.090 mg/L (90 µg/L), or 3) whether instead of issuing a national primary drinking water regulation, the EPA should withdraw the Agency's February 11, 2011, determination to regulate perchlorate in drinking water based on new information that indicates that perchlorate does not occur in public water systems with a frequency and at levels of public health concern and there may not be a meaningful opportunity for health risk reduction through a drinking water regulation. Under this last alternative, the final action would be a withdrawal of the determination to regulate and there would be no MCLG or national primary drinking water regulation for perchlorate.

DATES: Comments must be received on or before *[insert date 60 days after publication in the* Federal Register*]*. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before *[insert date 30 days after date of publication in the* Federal Register*]*.

ADDRESSES: Submit your comments, identified by Docket ID No. **EPA-HQ-OW-2018-0780**, at [HYPERLINK "http://www.regulations.gov"]. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit [HYPERLINK "http://www2.epa.gov/dockets/commenting-epa-dockets"].

FOR FURTHER INFORMATION CONTACT: Samuel Hernandez, Office of Ground Water and Drinking Water, Standards and Risk Management Division (Mail Code 4607M), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone number: (202) 564-1735; email address: hernandez.samuel@epa.gov.

SUPPLEMENTARY INFORMATION: This proposed rule is organized as follows:

E. Can Systems Use Grandfathered Data to Satisfy the Initial Monitoring Requirement?

IX. Safe Drinking Water Act Right to Know Requirements

A. What are the Consumer Confidence Report Requirements?

B. What are the Public Notification Requirements?

X. Treatment Technologies

A. What are the Best Available Technologies?

B. What are the Small System Compliance Technologies?

XI. Rule Implementation and Enforcement

A. What are the Requirements for Primacy?

B. What are the State Record Keeping Requirements?

C. What are the State Reporting Requirements?

XII. Health Risk Reduction Cost Analysis

A. Identifying Affected Entities

B. Method for Estimating Costs

C. Method for Estimating Benefits

D. Comparison of Costs and Benefits

XIII. Uncertainty Analysis

A. Uncertainties in the MCLG Derivation

B. Uncertainties in the Economic Analysis

XIV. Request for Comment on Proposed Rule

XV. Request for Comment on Potential Regulatory Determination Withdrawal

XVI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563 Improving Regulation and Regulatory Review

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

C. Paperwork Reduction Act

D. Regulatory Flexibility Act (RFA)

E. Unfunded Mandates Reform Act

F. Executive Order 13132: Federalism

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

H. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks

I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

J. National Technology Transfer and Advancement Act of 1995

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

XVII. Consultations with the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

XVIII. References

I. General Information

A. What is the EPA Proposing?

This action contains a proposal and three alternatives for public comment. First, the EPA proposes to establish a Maximum Contaminant Level Goal (MCLG) and National Primary Drinking Water Regulation (NPDWR) for perchlorate in public water supplies. The EPA proposes an MCLG of 56 μg/L, and to regulate perchlorate in drinking water at an enforceable maximum contaminant level (MCL) of 56 μg/L.

The EPA is proposing an NPDWR for perchlorate in accordance with its February 11, 2011, (76 FR 7762) determination to regulate perchlorate under the SDWA. Based on the best available peer reviewed science at that time, the EPA found that perchlorate met the SDWA's three criteria for regulating a contaminant: 1) the contaminant may have an adverse effect on the health of persons, 2) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems (PWSs) with a frequency and at levels of public health concern, and 3) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

Second, as explained in more detail below, the EPA is soliciting comment on two alternative MCLG/MCL values of 18 µg/L and 90 µg/L respectively. Third, in light of new considerations that have come to the EPA's attention since it issued its positive regulatory determination in 2011, including information on lower levels of occurrence of perchlorate than the EPA had previously believed to exist and new analysis of the concentration that represents a level of health concern, this action also discusses and requests comment on an alternative action under which the EPA would withdraw its 2011 determination to regulate perchlorate. Under this alternative, there would be no MCLG or NPDWR for perchlorate.

B. Does This Action Apply to Me?

Entities that could potentially be affected include the following:

Category	**Examples of potentially affected entities**
Public water systems	Community water systems Non-transient, non-community water systems
State and tribal agencies	Agencies responsible for drinking water regulatory development and enforcement

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that could be affected by this action. To determine whether your facility or activities could be affected by this action, you should carefully examine this proposed rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the FOR FURTHER INFORMATION CONTACT section.

II. Background

A. What is Perchlorate?

Perchlorate is a negatively charged inorganic ion that is comprised of one chlorine atom bound to four oxygen atoms (ClO_4-), which is highly stable and mobile in the aqueous environment. Perchlorate comes from both natural and manmade sources. It is formed naturally via atmospheric processes and can be found within mineral deposits in certain geographical areas. It is also produced in the United States, and the most common compounds include ammonium perchlorate and potassium perchlorate used primarily as oxidizers in solid fuels to power rockets, missiles, and fireworks. For the general population, most perchlorate exposure is through the ingestion of contaminated food or drinking water.

B. Statutory Authority

Section 1412(b)(1)(A) of the SDWA requires the EPA to establish NPDWRs for contaminants that may have an adverse effect on the health of persons; that are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and where in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

C. Statutory Framework and Regulatory History

Section 1412(b)(1)(B)(i) of the SDWA requires the EPA to publish every five years a Contaminant Candidate List (CCL). The CCL is a list of drinking water contaminants that are known or anticipated to occur in public water systems and are not currently subject to the EPA drinking water regulations. The EPA uses the CCL to identify priority contaminants for regulatory decision-making and information collection. Contaminants listed on the CCL may require future regulation under the SDWA. The EPA included perchlorate on the first, second, and third CCLs published in 1998, 2005, and 2009.

Once listed on the CCL, the Agency continues to collect data on CCL contaminants to better understand their potential health effects and to determine the levels at which they occur in drinking water. Section 1412(b)(1)(B)(ii) requires that, every five years, the EPA, after public comment, issue a determination whether or not to regulate at least five contaminants on the CCL. For any contaminant that the EPA determines meets the criteria for regulation, under Section 1412(b)(1)(E), the EPA must issue a proposed national primary drinking water regulation within two years and issue a final regulation 18 months after the proposal (which may be extended by 9 months).

As part of its responsibilities under the SDWA, the EPA implements section 1445(a)(2), "Monitoring Program for Unregulated Contaminants." This section requires that once every five years, the EPA issue a list of no more than 30 unregulated contaminants to be monitored by public water system. This monitoring is implemented through the Unregulated Contaminant Monitoring Rule (UCMR), which collects data from community water systems (CWS) and non-transient, non-community water systems (NTNCWS). The UCMR collects data from a census of large water systems (serving more than 10,000 people) and from a statistically representative sample of small water systems. On September 17, 1999, the EPA published its first UCMR (64 FR 50556) which required all large systems and a representative sample of small systems to monitor for perchlorate and 25 other contaminants (USEPA, 1999, 2000b).

The EPA and other federal agencies asked the National Research Council (NRC) to evaluate the health implications of perchlorate ingestion. The NRC concluded that perchlorate exposure inhibits the transport of iodide[1] into the thyroid by a protein molecule knows as the sodium/iodide symporter (NIS), which may lead to decreases in two hormones, thyroxine (T3) and triiodothyronine (T4) and increases in thyroid-stimulating hormone (TSH) [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a1mn5hjprkt","properties":{"formattedCitation":"(National Research Council (NRC), 2005b)","plainCitation":"(National Research Council (NRC), 2005b)","noteIndex":0},"citationItems":[{"id":350,"uris":["http://zotero.org/groups/945096/items/TN6HMC9D"],"uri":["http://zotero.org/groups/945096/items/TN6HMC9D"],"itemData":{"id":350,"type":"book","title":"Health Implications of Perchlorate Ingestion","publisher":"National Academies Press","publisher-place":"Washington, DC","event-place":"Washington, DC","author":[{"literal":"National Research Council (NRC)"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-

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[1] For the purposes of this FRN, "iodine" will be used to refer to dietary intake before entering the body. Once in the body, "iodide" will be used to refer to the ionic form.

language/schema/raw/master/csl-citation.json"}]. Additionally, the NRC concluded that the most sensitive population to perchlorate exposure are “the fetuses of pregnant women who might have hypothyroidism or iodide deficiency” (p. 178). The EPA established a reference dose (RfD) consistent with the recommended National Research Council RfD of 0.7 μg/kg/day for perchlorate. The reference dose is an estimate of a daily exposure to humans that is likely to be without an appreciable risk of adverse effects. This RfD was based on a study [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a3u94lt6me","properties":{"formattedCitation":"(Greer, Goodman, Pleus, & Greer, 2002)","plainCitation":"(Greer, Goodman, Pleus, & Greer, 2002)","noteIndex":0},"citationItems":[{"id":387,"uris":["http://zotero.org/groups/945096/items/6AKUNIX6"],"uri":["http://zotero.org/groups/945096/items/6AKUNIX6"],"itemData":{"id":387,"type":"article-journal","title":"Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans","container-title":"Environmental Health Perspectives","page":"927","volume":"110","issue":"9","author":[{"family":"Greer","given":"Monte A."},{"family":"Goodman","given":"Gay"},{"family":"Pleus","given":"Richard C."},{"family":"Greer","given":"Susan E."}],"issued":{"date-parts":[["2002"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] of perchlorate’s inhibition of radioactive iodine uptake in healthy adults and the application of an uncertainty factor of 10 for intraspecies

variability [ADDIN ZOTERO_ITEM CSL_CITATION
{"citationID":"0oHz805e","properties":{"formattedCitation":"(USEPA, 2005b)","plainCitation":"(USEPA, 2005b)","noteIndex":0},"citationItems":[{"id":980,"uris":["http://zotero.org/groups/945096/items/LHANJBR6"],"uri":["http://zotero.org/groups/945096/items/LHANJBR6"],"itemData":{"id":980,"type":"article","title":"Integrated Risk Information System (IRIS) Chemical Assessment Summary: Perchlorate (ClO4-) and Perchlorate Salts","publisher":"USEPA National Center for Environmental Assessment","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

In October 2008, the EPA published a preliminary regulatory determination not to regulate perchlorate in drinking water and requested public comment (73 FR 60262). In that preliminary determination, the EPA tentatively concluded that perchlorate did not occur with a frequency and at levels of public health concern and that development of a regulation did not present a meaningful opportunity for health risk reduction for persons served by public water systems. The EPA derived and used a Health Reference Level (HRL) of 15 μg/L based on the RfD of 0.7 μg/kg/day in making this conclusion [ADDIN ZOTERO_ITEM CSL_CITATION
{"citationID":"FZ6WMtAv","properties":{"formattedCitation":"(USEPA, 2008a)","plainCitation":"(USEPA, 2008a)","noteIndex":0},"citationItems":[{"id":934,"uris":["http://zotero.org/groups/945096/item

s/HBX88QM9"],"uri":["http://zotero.org/groups/945096/items/HBX88QM9"],"itemData":{"id":934,"type":"article-journal","title":"Drinking water: Preliminary regulatory determination on perchlorate","container-title":"Federal Register","volume":"73","issue":"198","abstract":"SUMMARY: This action presents EPA's preliminary regulatory determination for perchlorate in accordance with the Safe Drinking Water Act (SDWA). The Agency has determined that a national primary drinking water regulation (NPDWR) for perchlorate would not present \"a meaningful opportunity for health risk reduction for persons served by public water systems." The SDWA requires EPA to make determinations every five years of whether to regulate at least five contaminants on the Contaminant Candidate List (CCL). EPA included perchlorate on the first and second CCLs that were published in the Federal Register on March 2, 1998 and February 24, 2005. Most recently, EPA presented final regulatory determinations regarding 11 contaminants on the second CCL in a notice published in the Federal Register on July 30, 2008. In today's action, EPA presents supporting rationale and requests public comment on its preliminary regulatory determination for perchlorate. EPA will make a final regulatory determination for perchlorate after considering comments and information provided in the 30-day comment period following this notice. EPA plans to publish a health advisory for perchlorate at the time the Agency publishes its final regulatory determination to provide State and local public health officials with technical information that they may use in addressing local contamination.","ISSN":"ISSN 0097-6326 EISSN 2167-2520","shortTitle":"Federal Register","journalAbbreviation":"Fed.

Reg.","language":"English","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2008"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Based primarily on the UCMR 1 occurrence data, the EPA estimated that less than 1% of drinking water systems (serving approximately 1 million people) had perchlorate levels above the HRL of 15 μg/L. Based on this information the Agency determined that perchlorate did not occur frequently at levels of health concern. The EPA also determined that there was not a meaningful opportunity for a NPDWR to reduce health risks.

In January 2009 the EPA published an interim health advisory for perchlorate of 15 μg/L, consistent with the HRL derivation for perchlorate of 15 μg/L described above. Health Advisories are non-enforceable and non-regulatory and provide technical information to state agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. Health Advisories provide the public, including the most sensitive populations, with a margin of protection from a lifetime of exposure. For perchlorate, the health advisory was developed for subchronic exposure (USEPA 2008d).

In August 2009, the EPA published a supplemental request for comment with a new analysis that derived potential alternative HRLs for 14 life stages, including infants and children. The analysis used the RfD of 0.7 μg/kg/day and life stage-specific bodyweight and exposure information (74 FR 41883; USEPA, 2009a). After careful consideration of public comments on the October 2008 and August 2009 notices, on February 11, 2011, the EPA published its determination to regulate perchlorate (76 FR 7762; USEPA, 2011a). The Agency stated then that when considering the alternative HRL benchmarks described in the 2009 notice, the likelihood of perchlorate to occur at levels of concern had significantly increased in comparison to the levels described on the 2008 preliminary negative determination. The EPA concluded that as many as 16 million people could potentially be exposed to perchlorate at levels of concern, up from 1 million people originally described in the 2008 notice.

In its 2011 determination, the Agency found that perchlorate may have an adverse effect on the health of persons, that it is known to occur in public drinking water systems with a frequency and at levels that present a public health concern, and in the judgment of the Administrator, regulation of perchlorate presented a meaningful opportunity for health risk reduction for persons served by public water systems. As a result of the determination, and as required by Section 1412(b)(1)(E), the EPA initiated the process to develop an MCLG and NPDWR for perchlorate as described in this notice.

In September 2012, the U.S. Chamber of Commerce (the Chamber) submitted to the EPA a Request for Correction under the Information Quality Act regarding the EPA's regulatory determination. In the request, the Chamber claimed that the UCMR 1 data did not comply with data quality guidelines and were not representative of current conditions. In response to this request, the EPA reassessed the data and removed certain source water samples that could be paired with appropriate follow-up samples located at the entry point to the distribution system.

The EPA also updated the UCMR 1 data for systems in California and Massachusetts using state compliance data to reflect current occurrence conditions after state regulatory limits for perchlorate were implemented.

In response to a lawsuit brought to enforce the deadlines in Section 1412(b)(1)(E), the U.S. District Court for the Southern District of New York entered a consent decree, requiring the EPA to propose an NPDWR with a proposed MCLG for perchlorate in drinking water no later than October 31, 2018, and finalize an NPDWR and MCLG for perchlorate in drinking water no later than December 19, 2019. The deadline for the EPA to propose an NPDWR with a proposed MCLG for perchlorate in drinking water was later extended to May 28, 2019. The consent decree is available in the docket for today's proposed rule.

III. Assessment and Modeling of the Health Effects of Perchlorate

Perchlorate inhibits uptake of iodide into the thyroid gland by competitively binding to the protein that transports iodide with the NIS from blood to the thyroid gland (ATSDR, 2008; Greer et al., 2002; NRC, 2005; SAB 2013; Taylor et al~~. 2015~~., 2013). Iodide is necessary for the synthesis of thyroid hormones and decreased iodide uptake into the thyroid can adversely affect thyroid hormone production (SAB for the U.S. EPA, 2013; Blount et al., 2006; Steinmaus et al., 2007, 2013, 2016, McMullen et al., 2017; Knight et al., 2018). These changes in thyroid hormone levels in a pregnant woman may be linked to changes in the neurodevelopment of her offspring (SAB for the U.S. EPA, 2013; Korevaar et al., 2016; Fan and Wu, 2016; Wang et al., 2016; Alexander et al., 2017; Thompson et al., 2018). In addition, alterations in thyroid homeostasis may impact other body systems including the reproductive (Alexander et al., 2017; Hou et al., 2016; Maraka et al., 2016) and cardiovascular systems (Asvold et al., 2012; Sun et al., 2017).

More specifically, exposure to perchlorate is known to inhibit the uptake of iodide by the thyroid gland through the NIS (NRC, 2005; SAB for the U.S. EPA, 2013). A sufficient inhibition of iodide uptake results in iodide deficiency within the thyroid. Given that T3 and T4 require iodide for production, a decrease in intra-thyroidal iodide can result in decreased production of these hormones. This could in turn result in increased TSH, the hormone that acts on the thyroid gland to stimulate iodide uptake to increase thyroid hormone production [ADDIN ZOTERO_ITEM CSL_CITATION

{"citationID":"eF6zWm7L","properties":{"formattedCitation":"(ATSDR, 2008; Blount, Pirkle, Osterloh, Valentin-Blasini, & Caldwell, 2006; National Research Council (NRC), 2005; Steinmaus, Miller, Cushing, Blount, & Smith, 2013; Steinmaus et al., 2016)","plainCitation":"(ATSDR, 2008; Blount, Pirkle, Osterloh, Valentin-Blasini, & Caldwell, 2006; National Research Council (NRC), 2005; Steinmaus, Miller, Cushing, Blount, & Smith, 2013; Steinmaus et al., 2016)","noteIndex":0},"citationItems":[{"id":428,"uris":["http://zotero.org/groups/945096/items/UIANA947"],"uri":["http://zotero.org/groups/945096/items/UIANA947"],"itemData":{"id":428, "type":"bill","title":"Toxicological Profile for Perchlorates","author":[{"family":"ATSDR","given":""}],"issued":{"date-parts":[["2008"]]}}},{"id":203,"uris":["http://zotero.org/groups/945096/items/UW4TFPNI"],"uri":["http://zotero.org/groups/945096/items/UW4TFPNI"],"itemData":{"id":203,"type":"article-journal","title":"Urinary perchlorate and thyroid tormone levels in adolescent and adult men and women living in the United States","container-title":"Environmental Health Perspectives","page":"1865-1871","volume":"114","issue":"12","source":"CrossRef","DOI":"10.1289/ehp.9466","ISSN":"0091-6765","language":"en","author":[{"family":"Blount","given":"Benjamin C."},{"family":"Pirkle","given":"James L."},{"family":"Osterloh","given":"John D."},{"family":"Valentin-Blasini","given":"Liza"},{"family":"Caldwell","given":"Kathleen L."}],"issued":{"date-parts":[["2006"]]}}},{"id":349,"uris":["http://zotero.org/groups/945096/items/TN6HMC9D"],"uri":["http://zotero.org/groups/945096/items/TN6HMC9D"],"itemData":{"id":349,"type":"book","title":"Health Implications of Perchlorate Ingestion","publisher":"National Academies Press","publisher-place":"Washington, DC","event-place":"Washington, DC","author":[{"literal":"National Research Council (NRC)"}],"issued":{"date-parts":[["2005"]]}}},{"id":39,"uris":["http://zotero.org/groups/945096/items/35VPNIKR"],"uri":["http://zotero.org/groups/945096/items/35VPNIKR"],"itemData":{"id":39,"type":"article-journal","title":"Combined effects of perchlorate, thiocyanate, and iodine on thyroid function in the national health and nutrition examination survey 2007-8","container-title":"Environmental research","volume":"123","source":"www.ncbi.nlm.nih.gov","abstract":"Perchlorate, thiocyanate, and low iodine intake can all decrease iodide intake into the thyroid gland. This can reduce thyroid hormone production since iodide is a key component of thyroid hormone. Previous research has suggested that each of these factors ...","URL":"https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3857960/","DOI":"10.1016/j.envres.2013.01.005","note":"PMID: 23473920","language":"en","author":[{"family":"Steinmaus","given":"Craig"},{"family":"Miller","given":"Mark D."},{"family":"Cushing","given":"Lara"},{"family":"Blount","given":"Benjamin C."},{"family":"Smith","given":"Allan H."}],"issued":{"date-parts":[["2013",5]]},"accessed":{"date-parts":[["2017",5,5]]}}},{"id":211,"uris":["http://zotero.org/groups/945096/items/H4FH49VS"],"uri":["http://zotero.org/groups/945096/items/H4FH49VS"],"itemData":{"id":211,"type":"article-journal","title":"Thyroid hormones and moderate exposure toperchlorate during pregnancy in women in southern California","container-title":"Environmental Health Perspectives","page":"861-867","volume":"124","issue":"6","source":"PubMed","abstract":"BACKGROUND: Findings from national surveys suggest that everyone in the United States is exposed to perchlorate. At high doses, perchlorate, thiocyanate, and nitrate inhibit iodide uptake into the thyroid and decrease thyroid hormone production. Small changes in thyroid hormones during pregnancy, including changes within normal reference ranges, have been linked to cognitive function

declines in the offspring.\nOBJECTIVES: We evaluated the potential effects of low environmental exposures to perchlorate on thyroid function.\nMETHODS: Serum thyroid hormones and anti-thyroid antibodies and urinary perchlorate, thiocyanate, nitrate, and iodide concentrations were measured in 1,880 pregnant women from San Diego County, California, during 2000-2003, a period when much of the area's water supply was contaminated from an industrial plant with perchlorate at levels near the 2007 California regulatory standard of 6 μg/L. Linear regression was used to evaluate associations between urinary perchlorate and serum thyroid hormone concentrations in models adjusted for urinary creatinine and thiocyanate, maternal age and education, ethnicity, and gestational age at serum collection.\nRESULTS: The median urinary perchlorate concentration was 6.5 μg/L, about two times higher than in the general U.S.\nPOPULATION: Adjusted associations were identified between increasing log10 perchlorate and decreasing total thyroxine (T4) [regression coefficient (β) = -0.70; 95% CI: -1.06, -0.34], decreasing free thyroxine (fT4) (β = -0.053; 95% CI: -0.092, -0.013), and increasing log10 thyroid-stimulating hormone (β = 0.071; 95% CI: 0.008, 0.133).\nCONCLUSIONS: These results suggest that environmental perchlorate exposures may affect thyroid hormone production during pregnancy. This could have implications for public health given widespread perchlorate exposure and the importance of thyroid hormone in fetal neurodevelopment.\nCITATION: Steinmaus C, Pearl M, Kharrazi M, Blount BC, Miller MD, Pearce EN, Valentin-Blasini L, DeLorenze G, Hoofnagle AN, Liaw J. 2016. Thyroid hormones and moderate exposure to perchlorate during pregnancy in women in Southern California. Environ Health Perspect

124:861-867;

http://dx.doi.org/10.1289/ehp.1409614.","DOI":"10.1289/ehp.1409614","ISSN":"1552-9924","note":"PMID: 26485730\nPMCID: PMC4892913","journalAbbreviation":"Environ. Health Perspect.","language":"eng","author":[{"family":"Steinmaus","given":"Craig"},{"family":"Pearl","given":"Michelle"},{"family":"Kharrazi","given":"Martin"},{"family":"Blount","given":"Benjamin C."},{"family":"Miller","given":"Mark D."},{"family":"Pearce","given":"Elizabeth N."},{"family":"Valentin-Blasini","given":"Liza"},{"family":"DeLorenze","given":"Gerald"},{"family":"Hoofnagle","given":"Andrew N."},{"family":"Liaw","given":"Jane"}],"issued":{"date-parts":[["2016",6]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. For populations with developing brains (e.g., fetuses, neonates, and children), disruptions in homeostatic thyroid hormone function can result in adverse neurodevelopmental effects (Alexander et al., 2017; Glinoer & Delange, 2000; Glinoer & Rovet, 2009; SAB for the U.S. EPA, 2013). Specifically, decreased maternal thyroid hormone levels during pregnancy, including in the hypothyroxinemic range[2], have been linked to decrements in neurocognitive function in offspring (Alexander et al., 2017; Thompson et al., 2018; Wang et al., 2016). There is also limited evidence to suggest an association with other

[2] Maternal hypothyroxinemia is defined as TSH in the reference range and fT4 in the lower percentiles. The SAB notes that hypothyroxinemia has been defined by a "variety of cutoffs…ranging from fT4 below the 10th or 5th percentiles to below the 2.5th percentile" (SAB, 2013, p.10) in the population.

adverse neurodevelopmental outcomes including ADHD, expressive language delay, reduced school performance, autism, and delayed cognitive development (Alexander et al., 2017; Ghassabian, Bongers-Schokking, Henrichs, Jaddoe, & Visser, 2011; Gyllenberg et al., 2016; Henrichs et al., 2010; Korevaar et al., 2016, Noten et al., 2015; Pop et al., 2003, 1999; SAB for the U.S. EPA, 2013; van Mil et al., 2012).

The difficulty in estimating the likelihood and magnitude of the potential implications of perchlorate's mode of action on expressed neurodevelopmental health effects in humans exposed to perchlorate during development is the lack of robust epidemiological studies, especially in sensitive populations. Therefore, based on the known mode of action of perchlorate the Agency estimated potential health risks using a novel approach suggested by the EPA's Science Advisory Board (SAB for the U.S. EPA, 2013). The EPA's approach to estimating perchlorate risks has evolved over time with improved research and modeling capabilities. The following sections describe information sources the EPA used in its assessment as well as the regulatory process followed by the Agency in its decision making.

A. 2008 Preliminary Regulatory Determination

In 2005, at the request of the EPA and other federal agencies, the NRC evaluated the health implications of perchlorate ingestion. The NRC concluded that perchlorate exposure could inhibit the transport of iodide into the thyroid, leading to thyroid hormone deficiency (NRC, 2005). A significant inhibition of iodide uptake results in intra-thyroid iodide deficiency, decreased synthesis of T3 and T4, and increased TSH. The NRC also concluded that a prolonged decrease of thyroid hormones is potentially more likely to have adverse effects in sensitive populations (e.g., the fetuses of pregnant women who might have hypothyroidism or iodide deficiency). Based on these findings, the NRC recommended a reference dose of 0.7 μg/kg/day.

Based on NRC's analysis, the EPA established a perchlorate reference dose (RfD) of 0.7 μg/kg/day in 2005 (USEPA, 2005). This value was based on a no observed effect level (NOEL) of 7 μg/kg/day identified from a study (Greer, Goodman, Pleus, & Greer, 2002) of perchlorate's inhibition of radioactive iodine uptake in healthy adults and the application of an uncertainty factor of 10 for intraspecies variability.

As discussed above, in 2008, the EPA derived an HRL of 15 μg/L using the RfD of 0.7 μg/kg/day, a default bodyweight of 70 kg, a default drinking water consumption rate of 2 L/day, and a perchlorate-specific relative source contribution (RSC) of 62 percent that was derived for a pregnant woman (USEPA, 2008a) (73 FR 60262). The RSC is the percentage of the RfD remaining for drinking water after other sources of exposure to perchlorate (i.e., food) have been considered. The EPA's HRL was calculated to offer a margin of protection against adverse health effects to the subpopulation identified by the NAS as likely the most sensitive to the effects of perchlorate exposure, fetuses.

B. 2009 Supplemental Request for Comment and 2011 Final Regulatory Determination

The EPA received over 33,000 comments in response to its 2008 preliminary determination to not regulate perchlorate (USEPA, 2011a). After reviewing the comments, the EPA developed alternative HRLs for other sensitive populations in addition to fetuses of pregnant women. The EPA developed alternative HRLs for 14 life stages including infants and children. The EPA also evaluated the occurrence of perchlorate at levels above these alternative HRLs using the UCMR 1 occurrence data.

The analysis used the RfD of 0.7 μg/kg/day and life stage-specific bodyweight and exposure information (i.e., drinking water intake, RSC) for each of the 14 life stages evaluated. The resulting HRLs ranged from 1 μg/L to 47 μg/L. In August 2009, the EPA published a supplemental request for comment with the new analysis and HRLs (74 FR 41883; USEPA, 2009a). After careful consideration of public comments, on February 11, 2011, the EPA published its final determination to regulate perchlorate (76 FR 7762; USEPA, 2011a).

C. Science Advisory Board Recommendations

As required by Section 1412(d) of the SDWA, as part of the NPDWR development process, the EPA requested comments from the Science Advisory Board (SAB) in 2012, seeking guidance on how best to consider and interpret the life stage information, the epidemiologic and biomonitoring data since the NRC report, physiologically-based pharmacokinetic (PBPK) analyses, and the totality of perchlorate health information to derive an MCLG for perchlorate. The SAB recommended the following:

- derive a perchlorate MCLG that addresses sensitive life stages through physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling based upon perchlorate's mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters;

- expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;
- utilize a mode-of-action framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition – to thyroid hormone changes – and finally to neurodevelopmental impacts; and
- "Extend the [BBDR] model expeditiously to…provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages" (SAB for the U.S. EPA, 2013, p. 19).

This SAB-proposed framework would incorporate the previous endpoint of iodide uptake inhibition that was the basis for the RfD as part of a broader and more comprehensive framework that links perchlorate exposure to adverse neurodevelopmental outcomes. It also focuses on the smaller changes in thyroid hormones (specifically free T4 (fT4)) that are associated with maternal hypothyroxinemia and subsequent adverse neurodevelopmental health effects rather than the significant changes in thyroid hormones (both fT4 and TSH) that are associated with hypothyroidism.

D. Perchlorate Model Development and Peer Reviews

To address the SAB recommendations, the EPA revised an existing PBPK/PD model that describes the dynamics of perchlorate, iodide, and thyroid hormones in a woman during the third trimester of pregnancy (Lumen, Mattie, & Fisher, 2013; USEPA, 2009b). The EPA also created its own Biologically Based Dose Response (BBDR) models that included the additional sensitive life stages identified by the SAB, i.e., breast- and bottle-fed neonates and infants (SAB for the U.S. EPA, 2013, p. 19).

To determine whether the Agency had implemented the SAB recommendations for modeling thyroid hormone changes, the EPA convened an independent peer review panel to evaluate the BBDR models in January 2017 (External Peer Reviewers for USEPA, 2017). In addition to estimating effects on breast fed infants, several reviewers recommended that the EPA shift the primary focus of its analysis to modeling the exposure implications to the fetus during early pregnancy. This was based on the knowledge that fetuses lack a functioning thyroid gland until approximately 16 gestational weeks and the substantial epidemiological evidence linking early pregnancy low fT4 levels with adverse neurodevelopmental outcomes [ADDIN EN.CITE <EndNote><Cite><Author>Morreale de Escobar</Author><Year>2004</Year><RecNum>49</RecNum><DisplayText>(G Morreale de Escobar, Obregón, & Escobar del Rey, 2004)</DisplayText><record><rec-number>49</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1437077734">49</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Morreale de Escobar, G</author><author>Obregón, M J</author><author>Escobar del Rey, F</author></authors></contributors><titles><title>Role of thyroid hormone during early brain development</title><secondary-title>European Journal of Endocrinology</secondary-title></titles><periodical><full-title>European Journal of Endocrinology</full-title></periodical><pages>U25-U37</pages><volume>151</volume><number>Suppl 3</number><dates><year>2004</year><pub-dates><date>November 1, 2004</date></pub-dates></dates><urls><related-urls><url>http://www.eje-online.org/content/151/Suppl_3/U25.abstract</url></related-urls></urls><electronic-resource-num>10.1530/eje.0.151U025</electronic-resource-num></record></Cite></EndNote>]. Specifically, the SAB recommended that the EPA use specific sensitive populations to develop the MCLG for perchlorate: "the fetuses of hypothyroxinemic pregnant women, and infants exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women" (SAB for the U.S. EPA, 2013, p. 19).

The EPA considered all recommendations from the 2017 peer review. The previously developed BBDR model describing perchlorate's effects in the third trimester (Lumen, Mattie, & Fisher, 2013; USEPA, 2009b) was calibrated only for that phase of pregnancy, not for the first trimester, and lacked a description of TSH signaling (feedback) that becomes significant as individuals become hypothyroxinemic or hypothyroid. In particular, this signaling was considered necessary to accurately predict responses of women with very low iodine intake, which was also part of the 2017 peer review recommendations. Therefore, the Lumen et al., (2009b) model needed to be revised to address these recommendations and the EPA implemented those changes needed to increase the scientific rigor of the model and modeling results. These modifications include:

- extending the model to early pregnancy;
- incorporating biological feedback control of hormone production via TSH signaling, such that the model can describe lower levels of iodide nutrition;
- calibrating the model and evaluating its behavior for upper and lower percentiles of the population, as well as the population median; and
- conducting an uncertainty analysis for key parameters.

The EPA convened a second independent peer review panel in January 2018 to evaluate these updates to the BBDR model. The EPA also presented several approaches in the draft *Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water* (MCLG Approaches Report) to link the thyroid hormone changes in a pregnant mother predicted by the BBDR model to neurodevelopmental effects using evidence from the epidemiological literature (External Peer Review for U.S. EPA, 2018). The 2018 peer review identified a variety of strengths and limitations of the modeling (to be discussed in more detail later in this notice). The peer review panel was largely supportive of the efforts described in the MCLG Approaches Report, as evidenced by the following from the peer review final report:

Overall, the panel agreed that the EPA and its collaborators have prepared a highly innovative state-of-the-science set of quantitative tools to evaluate *neurodevelopmental effects that could arise from drinking water exposure to perchlorate. While there is always room for improvement of the models, with limited additional work to address the committee's comments [in the peer-reviewed report], the current models are fit-for-purpose to determine an MCLG (External Peer Reviewers for U.S. EPA, 2018, p. 2).*

The EPA also presented an alternative, population-based approach evaluating the shift in the proportion of the population that would fall below a hypothyroxinemic cut point, given exposure to perchlorate (Section 7 of the MCLG Approaches Report). This approach does not directly connect the BBDR output to a neurodevelopmental endpoint. However, for pregnant women in early pregnancy, this shift could be related to avoiding an increase in the population of offspring's risk of adverse neurodevelopmental impacts. The 2018 peer review identified strengths associated with this approach, including

1) the central premise, that hypothyroxinemia is associated with adverse neurodevelopmental effects is supported by a large number of studies, including categorical studies; 2) this approach encompasses a variety of adverse neurodevelopmental outcomes, as indicated by these studies, rather than focusing on one or a limited number of adverse outcomes, as with the two-stage approach; and 3) this approach avoids all of the uncertainties associated with determining a quantitative relationship between a specific maternal fT4 level and the magnitude an adverse neurodevelopmental effect. (External Peer Reviewers for U.S. EPA, 2018, p. 7)

The peer reviewers expressed concern about hypothyroxinemia being a precursor effect, rather than an adverse health outcome, which they argued may create difficulties in explaining the basis for an MCLG based on this approach to some audiences. However, the EPA has used precursor effects as the basis for setting regulatory and non-regulatory limits previously. The peer-review panel also expressed concern that a standard definition of hypothyroxinemia has not yet been established, as clinicians use varying fT4 thresholds to define their own working definition of the condition. This also could lead to difficulties communicating the population at risk for developing this precursor effect as a result of perchlorate exposure.

Ultimately, the EPA chose to develop the MCLG using dose-response functions from the epidemiological literature to estimate neurodevelopmental impacts in the offspring of pregnant women exposed to perchlorate. The EPA selected this proposed approach because it is consistent with the SDWA's definition of an MCLG to avoid adverse health effects and because it is most consistent with the SAB recommendations. The EPA is requesting public comment in Section XIV on the adequacies and uncertainties of the methodology to derive the MCLG including the decision not to pursue this population-based approach for setting the MCLG.

Based on the comments of the peer reviewers, the EPA's final analysis informing the derivation of the MCLG and benefits of avoided perchlorate exposure is based upon a 2-step approach to modeling the neurodevelopmental effects on offspring of pregnant women exposed to perchlorate in drinking water (see Figure 1). In summary, because of the known mode of action, the lack of epidemiological studies particularly in the sensitive populations and the direction of the SAB to use a "data-driven approach [which] represents a more rigorous way to address differences in biology and exposure between adults and sensitive life stages" (p. 2, SAB 2013 for U.S. EPA), the EPA uses a combination of the BBDR model that simulates perchlorate potential impacts on maternal thyroid hormones during pregnancy and the epidemiology literature that relates incremental changes in maternal thyroid hormones to neurodevelopmental outcomes in children. The following sections describe the approach in greater detail, highlighting each step in which decisions and assumptions were made.

Figure 1. Two-Step Modeling Approach to Link Maternal Perchlorate Exposure to Measurable Adverse Neurodevelopmental Impacts in Offspring
[EMBED Visio.Drawing.15]

Note: Process figure does not imply the strength of scientific evidence.

E. Sensitive Population for Deriving MCLG

SDWA 1412(b)(4)(A) requires MCLGs to be set at a concentration in water "at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." SDWA 1412(b)(3)(C)(V) further requires that the EPA "consider the effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population." The EPA has interpreted these requirements to establish MCLGs that avoid adverse effects within the portions of the population that are at greater risk of adverse effects from exposure to the contaminant. The EPA is proposing an MCLG that is developed to protect the fetuses of a first trimester pregnant mother with low-iodine intake levels (i.e., 75 µg/kg/day), low fT4 levels (i.e., 10th percentile of an fT4 distribution for individuals with 75 µg/day iodine intake), and weak TSH feedback strength (i.e., TSH feedback is reduced to be approximately 60 percent less effective than for the median individual). The choice of this population is consistent with discussion by the NRC (2005), and the SAB (2013). The EPA believes that by protecting this population, the other sensitive populations (i.e., breast- and bottle-fed infants) will also be protected. This conclusion is based on the EPA's analysis of predictions of the impact of perchlorate on fT4 levels from the original EPA BBDR model (which was peer reviewed in January of 2017) and an analysis of the literature on the connection between altered thyroid hormones in these life stages, and neurodevelopmental outcomes.

The EPA's original BBDR model demonstrated that perchlorate had minimal impact on the thyroid hormone levels for 30-, 60-, and 90-day formula-fed infants, even at doses as high as 20 µg/kg/day. Specifically, the model demonstrated that "the range of iodine levels in formula is sufficient to almost entirely offset the effects of perchlorate exposure at 30, 60 and 90 days" [ADDIN EN.CITE <EndNote><Cite><Author>U.S. EPA</Author><Year>2016</Year><RecNum>246</RecNum><Suffix>`; p. 73</Suffix><DisplayText>(U.S. EPA, 2016; p. 73)</DisplayText><record><rec-number>246</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468339271">246</key></foreign-keys><ref-type name="Generic">13</ref-type><contributors><authors><author>U.S.

EPA,</author></authors><secondary-authors><author>Paul Schlosser, Teresa Leavens, and Santhini Ramasamy</author></secondary-authors></contributors><titles><title>Biologically based dose response models for the effect of perchlorate on thyroid hormones in the infant, breast feeding mother, pregnant mother, and fetus: model development, revision, and preliminary dose-response analyses </title><secondary-title>Peer Review Draft</secondary-title></titles><dates><year>2016</year></dates><urls></urls></record></Cite></EndNote>]. As a result of these findings the EPA concluded that any MCLG based on the fetus of the first trimester hypothyroxinemic pregnant mother would also protect the formula-fed infant.

To determine if the same would be true for the breast-fed infant, the EPA compared the predicted percent change in fT4 experienced at given doses of perchlorate for both the breast-fed infant and the first trimester pregnant mother at varying doses of iodine intake[3] (50 to 100 µg/day). Assuming 2 or 4 µg/kg/day of perchlorate, the first trimester hypothyroxinemic pregnant mother has a greater percent change in fT4 compared to the 30 and 60 day breast-fed infant at all maternal iodine intake levels evaluated, except for the 30 day breast-fed infant of a mother consuming only 50 µg/day iodine. However, given that the original BBDR model did not have a TSH feedback loop, T4, fT4, T3 and fT3 predictions for lactating mothers with less than 75 µg/day iodine intake were considered highly uncertain because the thyroid hormone levels had fallen into the hypothyroid range.

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[3]Given that the current version of the BBDR model contains a TSH feedback loop and the infant models previously developed did not contain this feedback loop, this comparison is done with the feedback loop turned off.

The Agency found that there are reports in the scientific literature suggesting that minor perturbations in thyroid hormone levels in the first trimester mother may adversely impact her offspring's neurodevelopment. Specifically, some studies show that children exposed gestationally to maternal hypothyroxinemia (without hypothyroidism) have a higher risk of reduced levels of global and specific cognitive abilities, as well as increased rates of behavior problems including greater dysregulation in early infancy and attentional disorders in childhood [ADDIN EN.CITE ADDIN EN.CITE.DATA]. Notably these effects are correlated with both degree [ADDIN EN.CITE ADDIN EN.CITE.DATA] and duration [ADDIN EN.CITE <EndNote><Cite><Author>Pop</Author><Year>2003</Year><RecNum>25</RecNum><DisplayText>(Pop et al., 2003)</DisplayText><record><rec-number>25</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1432047641">25</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Pop, V J</author><author>Brouwers, E P</author><author>Vader, H L</author><author>Vulsma, T</author><author>van Baar, A L</author><author>de Vijlder, J J</author></authors></contributors><titles><title>Maternal hypothyroxinemia during early pregnancy and subsequent child development: a 3-year follow-up study</title><secondary-title>Clinical Endocrinology</secondary-title></titles><periodical><full-title>Clinical Endocrinology</full-title></periodical><pages>282-288</pages><volume>59</volume><section>282</section><dates><year>2003</year></dates

><urls></urls></record></Cite></EndNote>] of maternal hypothyroxinemia [ADDIN EN.CITE <EndNote><Cite><Author>SAB</Author><Year>2013</Year><RecNum>50</RecNum><Suffix>`; p. 10</Suffix><DisplayText>(SAB, 2013; p. 10)</DisplayText><record><rec-number>50</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1437138201">50</key></foreign-keys><ref-type name="Government Document">46</ref-type><contributors><authors><author>SAB,</author></authors><secondary-authors><author>U.S. Environmental Protection Agency,</author></secondary-authors></contributors><titles><title>Advice on approaches to derive a maximum contaminant level goal for perchlorate. EPA-SAB-13-004</title></titles><dates><year>2013</year></dates><pub-location>Washington, DC</pub-location><urls></urls></record></Cite></EndNote>].

The EPA did not find analogous evidence linking minor perturbations in thyroid hormones during infancy to adverse neurodevelopmental outcomes in infants. This finding is consistent with conclusions by the California Environmental Protection Agency (CalEPA) in their assessment of a public health goal for perchlorate [ADDIN EN.CITE <EndNote><Cite ExcludeAuth="1"><Author>California Environmental Protection Agency (CalEPA)</Author><Year>2015</Year><RecNum>62</RecNum><Prefix>CalEPA`, </Prefix><Suffix>`; p. 90</Suffix><DisplayText>(CalEPA, 2015; p. 90)</DisplayText><record><rec-number>62</rec-number><foreign-keys><key app="EN" db-

id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1437413166">62</key></foreign-keys><ref-type name="Government Document">46</ref-type><contributors><authors><author>California Environmental Protection Agency (CalEPA),</author></authors><secondary-authors><author>Office of Environmental Health Hazard Assessment</author></secondary-authors></contributors><titles><title>Public health goal for perchlorate in drinking water</title></titles><dates><year>2015</year></dates><urls></urls></record></Cite></EndNote>].

Specifically, two studies evaluated both the impact of maternal hypothyroxinemia and infant fT4 levels on subsequent neurodevelopmental outcomes. [HYPERLINK \l "_ENREF_9" \o "Costeira, 2011 #7"] found that children born to mothers with low fT4 in the first trimester had increased odds of mild-to-severe delays in psychomotor development compared to children born to mothers with normal fT4 levels. However, the authors found that neonatal thyroid status (measured on day 3 after birth) did not influence development. Additionally, [HYPERLINK \l "_ENREF_17" \o "Henrichs, 2010 #928"] found in their evaluation that although maternal hypothyroxinemia was associated with language delay and nonverbal cognitive delay, the neonatal thyroid status (thyroid hormones measured in cord blood) did not explain the relationship between maternal hypothyroxinemia, early pregnancy, and children's cognitive impairment.

The SAB pointed to two lines of evidence supporting their suggestion of the infant as a potentially sensitive population to perchlorate: preterm infants that experience transient hypothyroxinemia of prematurity (THOP) and infants that experience congenital hypothyroidism (SAB for the U.S. EPA, 2013). Thus, sufficient thyroid hormone levels in infancy are necessary for the infant brain to develop properly. However, the best evidence linking perturbations in thyroid hormone levels to disrupted neurodevelopment for infants are in individuals with significant thyroid deficiencies manifesting as clinical conditions (e.g., THOP and congenital hypothyroidism). It is unclear and unknown if minor perturbations in thyroid hormones in infants, such as those that could be caused by environmental levels of perchlorate, would result in adverse neurodevelopmental outcomes similar to those seen in the literature for the offspring of first trimester pregnant mothers with hypothyroxinemia. Given the lack of evidence demonstrating minor perturbations in infant fT4 levels as being associated with neurodevelopmental outcomes, the EPA has concluded that it is appropriate to derive the perchlorate MCLG to protect the first trimester fetus of a pregnant mother with low-iodine intake. The EPA concludes that an MCLG calculated to offer a margin of protection against adverse health effects to these fetuses targets the most sensitive lifestage and will be protective of other potentially sensitive life stages as well.

F. BBDR Model Specification for the Sensitive Population

The BBDR model used to develop the proposed MCLG has two main components:

- a pharmacokinetic model for perchlorate and iodide, which describes chemical absorption, distribution, metabolism, and excretion of perchlorate and iodide; and
- a pharmacodynamic model, which describes the joint effect of varying perchlorate and iodide blood concentrations on thyroidal uptake of iodide and subsequent production of thyroid hormones, including fT4.

The pharmacokinetic model component contains a physiological description of a human mother and fetus during pregnancy (e.g., organ volumes, blood flows) and chemical-specific information (e.g., partition coefficients, volume of distribution, rate constants for transport, metabolism, and elimination) that enable a prediction of perchlorate and iodide internal concentration at the critical target (i.e., thyroidal sodium-iodide symporter of the mother) in association with a particular exposure scenario (route of exposure, age, dose level). This component of the model is similar to many other PBPK models. Because perchlorate does not undergo metabolism in vivo (Clewell et al., 2007), potential uncertainty from this factor of the model is avoided since it does not need to be described.

The pharmacodynamic component of the model uses this internal concentration to simulate how the chemical will act within a known mechanism of action to perturb host systems and lead to a toxic effect.

Thus, the BBDR model estimates serum thyroid hormone levels in the mother at specific gestational weeks, given specific levels of iodine intake, the TSH feedback loop strength, and perchlorate doses. As noted above, to be health protective the EPA chose to model a sensitive individual (an adult woman with low iodine through the first trimester of pregnancy) to derive an MCLG, thereby protecting both this target sensitive population with an adequate margin of safety and those who are less sensitive with an even larger margin of safety.

The BBDR model simulates perchlorate's impact on thyroid hormones at each gestational week from conception to week 16. To derive the MCLG, the EPA selected outputs for gestational week 13 to correspond with the thyroid hormone data reported in Korevaar et al., (2016), which is the basis for the Agency's quantitative relationship between maternal thyroid hormone levels and neurodevelopmental impacts.

Individuals with low iodine intake have increased sensitivity to perchlorate's impact on thyroid hormone levels because the functional iodide reserve of the hypothalamic-pituitary-thyroid (HPT) system is limited [ADDIN EN.CITE <EndNote><Cite><Author>Leung</Author><Year>2010</Year><RecNum>1160</RecNum><DisplayText>(Leung, Pearce, & Braverman, 2010)</DisplayText><record><rec-number>1160</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1495206437">1160</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Leung, A. M.</author><author>Pearce,</author><author>Braverman</author></authors></contributors><titles><title>Perchlorate, iodine and the thyroid</title><secondary-title>Best Practice and Research: Clinical Endocrinology and Metabolism</secondary-title><alt-title>Best Pract Res

Clin Endocrinol Metab</alt-title><short-title>Best Practice and Research: Clinical Endocrinology and Metabolism</short-title></titles><alt-periodical><full-title>Best Pract Res Clin Endocrinol Metab</full-title></alt-periodical><pages>133-141</pages><volume>24</volume><number>1</number><dates><year>2010</year></dates><isbn>ISSN 1521-690X
EISSN 1532-1908</isbn><label>755955</label><work-type>Review</work-type><urls><related-urls><url>http://dx.doi.org/10.1016/j.beem.2009.08.009</url></related-urls></urls><electronic-resource-num>10.1016/j.beem.2009.08.009</electronic-resource-num><language>English</language></record></Cite></EndNote>]. The EPA selected an iodine intake level of 75 µg/day to simulate an individual with low-iodine intake. This value represents an intake between the 15th and 20th percentile of the women of child bearing age population distribution of estimated iodine intake from the National Health and Nutrition Examination Survey (NHANES). The EPA considered using a lower iodine intake level of 50 µg/day, which represents approximately the 5th percentile of the NHANES distribution. At 50 µg/day of iodine intake, however, the BBDR model predicts TSH levels that would be elevated to within the clinically hypothyroid range before exposure to any perchlorate[4] (TSH

[4] For the purposes of this analysis, the EPA evaluated the American Thyroid Association's (ATA's) 2017 recommendations for defining hypothyroidism [ADDIN EN.CITE <EndNote><Cite><Author>Alexander</Author><Year>2017</Year><RecNum>1895</RecNum><DisplayText>(Alexander et al., 2017)</DisplayText><record><rec-number>1895</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1497970921">1895</key></foreign-keys><ref-type

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name="Journal Article">17</ref-type><contributors><authors><author>Alexander, E. K.</author><author>Pearce, E. N.</author><author>Brent, G. A.</author><author>Brown, R. S.</author><author>Chen, H.</author><author>Dosiou, C., </author><author>Sullivan, S.</author></authors></contributors><titles><title>2017 Guidelines of the American Thyroid Association for the diagnosis and management of thyroid disease during pregnancy and the postpartum</title><secondary-title>Thyroid</secondary-title></titles><periodical><full-title>Thyroid</full-title></periodical><pages>315-389</pages><volume>27</volume><number>3</number><dates><year>2017</year></dates><urls></urls></record></Cite></EndNote>]. Specifically the ATA recommends "in the pregnancy setting, maternal hypothyroidism is defined as a TSH concentration elevated beyond the upper limit of the pregnancy-specific reference range" [ADDIN EN.CITE <EndNote><Cite><Author>Alexander</Author><Year>2017</Year><RecNum>1895</RecNum><Pages>332</Pages><DisplayText>(Alexander et al., 2017, p. 332)</DisplayText><record><rec-number>1895</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1497970921">1895</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Alexander, E. K.</author><author>Pearce, E. N.</author><author>Brent, G. A.</author><author>Brown, R. S.</author><author>Chen, H.</author><author>Dosiou, C., </author><author>Sullivan, S.</author></authors></contributors><titles><title>2017 Guidelines of the American Thyroid Association for the diagnosis and management of thyroid disease during pregnancy and the postpartum</title><secondary-title>Thyroid</secondary-title></titles><periodical><full-title>Thyroid</full-title></periodical><pages>315-389</pages><volume>27</volume><number>3</number><dates><year>2017</year></dates><urls></urls></record></Cite></EndNote>]. ATA goes on to state, in the absence of population- and trimester-specific reference ranges defined by a provider's institute or laboratory, that the TSH reference ranges should be obtained from similar patient populations. From their recommended studies with trimester-specific data on a U.S. population, Lambert-Meserlian et al. [ADDIN EN.CITE <EndNote><Cite ExcludeAuth="1"><Author>Lambert-Messerlian</Author><Year>2008</Year><RecNum>100</RecNum><DisplayText>(2008)</DisplayText><record><rec-number>100</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1443808320">100</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Lambert-Messerlian, Geralyn</author><author>McClain, Monica</author><author>Haddow, James E</author><author>Palomaki, Glenn E</author><author>Canick, Jacob A</author><author>Cleary-Goldman, Jane</author><author>Malone, Fergal D</author><author>Porter, T Flint</author><author>Nyberg, David A</author><author>Bernstein, Peter</author></authors></contributors><titles><title>First-and second-trimester thyroid hormone reference data in pregnant women: a FaSTER (First-and Second-Trimester Evaluation of Risk for aneuploidy) Research Consortium study</title><secondary-title>American journal of obstetrics and gynecology</secondary-title></titles><periodical><full-title>American journal of obstetrics and gynecology</full-title></periodical><pages>62-e1</pages><volume>199</volume><number>1</number><dates><year>2008</year></dates><publisher>Elsevier</publisher><isbn>0002-9378</isbn><urls></urls></record></Cite></EndNote>] is the largest U.S.-based population with a reference range upper bound of 3.37 mIU/L for the first trimester (and 3.35 mIU/L for the second trimester). Therefore, these values were used to compare to BBDR output TSH values in the first trimester (or second trimester in cases of gestational weeks 15 and 16) to determine the presence of hypothyroidism.

ranges between 4.51 and 5.41 milli-international units per liter (mIU/L) at zero dose of perchlorate when evaluating gestational weeks 12 or 13). In contrast, at 75 µg/day iodine, the BBDR modeled concentrations of serum fT4 and TSH are significantly reduced from the population median but are still within the euthyroid range. Thus, the intake of 75 µg/day is a better approximation of the sensitive population – the offspring of pregnant women who have low fT4.

TSH increases in response to decreases in T4 have been captured in numerous studies that document the relationship between these hormones[ADDIN EN.CITE ADDIN EN.CITE.DATA]. The EPA designed the BBDR model to depict this feedback regulation by adjusting a set of three parameters: the number of sodium-iodide symporter sites, the T4 synthesis rate, and the T3 synthesis rate. The BBDR model allows for variability in the strength of the TSH feedback by varying these parameters with a variable called "pTSH." For the MCLG analysis, the EPA used a pTSH value of 0.398, which is the ratio of a median value for TSH from NHANES (non-pregnant women) to the 97.5 percentile value from NHANES (non-pregnant women). This value represents an assumption that sensitive individuals with high TSH and average fT4 levels exist, and this is because the stimulus strength of TSH is proportionally weaker. The EPA chose to use a low TSH feedback coefficient to ensure the MCLG is protective of the sensitive population.

Example output from the BBDR model for gestational week 13 and a low TSH feedback coefficient is presented in [REF _Ref517525852 \h * MERGEFORMAT].

Table III-[SEQ Table * ARABIC]. Summary of BBDR Model Results for fT4 Levels: Pregnant Women at Gestational Week 13, Assuming Low (75 µg/day) Iodine Intake and with Muted TSH feedback strength[a][]

Perchlorate Dose (µg/kg/day)	Percentile fT4 (pmol/L)[b] (% decrease from 0 dose)			
	2.5th	5th	10th	50th
0	5.57	6.09	6.70	8.84
1	5.50 (-1.26%)	6.02 (-1.15%)	6.63 (-1.04%)	8.77 (-0.79%)
2	5.43 (-2.45%)	5.96 (-2.24%)	6.56 (-2.04%)	8.71 (-1.54%)
3	5.37 (-3.59%)	5.96 (-3.28%)	6.50 (-2.98%)	8.64 (-2.26%)
4	5.31 (-4.68%)	5.83 (-4.28%)	6.44 (-3.89%)	8.58 (-2.95%)
5	5.25 (-5.73%)	5.77 (-5.23%)	6.38 (-4.76%)	8.52 (-3.60%)
6	5.19 (-6.73%)	5.72 (-6.14%)	6.33 (-5.59%)	8.47 (-4.23%)
7	5.14 (-7.69%)	5.66 (-7.02%)	6.27 (-6.39%)	8.41 (-4.84%)

[a] pTSH = 0.398; see USEPA, (2018b) for additional information on pTSH.
[b] The 50th percentile is direct output from the BBDR model, and additional percentiles are estimated by assuming a normal distribution with a SD of 1.67. All of the examined study data demonstrated a positive skew, and overall the lognormal function demonstrated a better fit than a normal distribution. Despite this, the available study data only accounted for variation due to gestation week and did not account for variation in perchlorate and iodine intake in the measured populations. Because perchlorate and iodine can affect fT4 levels, and this relationship produced the estimated median BBDR values, the distribution around values estimated by the model from perchlorate and iodine intake should account for a small reduction in variation due to the effect of perchlorate and iodine intake. Additionally, as iodine has a demonstrated lognormal distribution with strong right skew (e.g. Blount et al., 2007) and is predicted to have a stronger effect on fT4 than perchlorate (see Section 3). The EPA assumed the error around predicted fT4 would likely be closer to normal than lognormal after accounting for perchlorate and iodine intake.

When modeling changes in fT4, the baseline level of fT4 affects the magnitude of changes seen as a result of perchlorate exposure. Therefore, to predict the impact of perchlorate exposure on the population distribution of fT4 for the identified sensitive population, the EPA estimated a distribution for fT4 plasma concentrations around the median modeled values based on fT4 data from studies that were used to calibrate the BBDR model (C. Li et al., 2014; Männistö et al., 2011; Zhang et al., 2016). The EPA assumed the variation around predicted fT4 concentrations for women with low fT4 of childbearing age would likely be close to normal after accounting for perchlorate and iodine intake, and thus estimated a combined standard deviation (SD) using the distributional information from each of the studies (C. Li et al., 2014; Männistö et al., 2011; Zhang et al., 2016). The EPA then used the estimated combined SD to predict a distribution of fT4 around the median fT4 estimated by the BBDR model. To protect the most sensitive population from adverse effects, the EPA chose to use the 10th percentile from this distribution of baseline fT4 to conduct its analyses to account for variability in thyroid hormones in the population[5].

G. Epidemiological Literature

The SAB recommended that the EPA integrate BBDR model results with data on neurodevelopmental outcomes from epidemiological studies. There is substantial epidemiological evidence that early pregnancy hypothyroxinemia is a risk factor for a variety of adverse neurodevelopmental outcomes, including those related to both cognition and behavior (Costeira et al., 2011; Finken, van Eijsden, Loomans, Vrijkotte, & Rotteveel, 2013; Ghassabian et al., 2014; Gyllenberg et al., 2016; Henrichs et al., 2010; Júlvez et al., 2013; Kooistra, Crawford, van Baar, Brouwers, & Pop, 2006; Korevaar et al., 2016; Y. Li et al., 2010;

[5] For a discussion on the details of the BBDR model, including uncertainties associated with the model the reader is directed to section 3.5 of the MCLG Approaches Report.

Oostenbroek et al., 2017; Päkkilä et al., 2015; Pop et al., 2003, 1999; ~~Román~~Roman et al., 2013; van Mil et al., 2012). These individual studies showing that maternal hypothyroxinemia is associated with offspring neurodevelopment are also supported by three meta-analyses (including one full systematic review), all of which conclude maternal hypothyroxinemia is associated with increased risk of cognitive delay, intellectual impairment, or lower scores on performance tests when considering the entire body of evidence on this topic [ADDIN EN.CITE ADDIN EN.CITE.DATA]. Additionally, the American Thyroid Association concludes that "overall, available evidence appears to show an association between hypothyroxinemia and cognitive development of the offspring" (Alexander et al., 2017, p. 337).

The EPA did not conduct a full systematic review and weight of evidence evaluation between maternal thyroid hormones and neurodevelopmental outcomes given: 1) the body of scientific literature regarding this association, and 2) the SAB recommendation that the EPA "consider available data on potential adverse health effects (neurodevelopmental outcomes) due to thyroid hormone level perturbations regardless of the cause of those perturbations" (p. 25). Instead, the EPA conducted a "methodologic approach to reviewing the literature" to evaluate the body of literature on this topic. This approach assisted in extrapolating the relationship modeled by the BBDR model to neurodevelopmental outcomes by concentrating on studies that allowed for evaluation of incremental changes in fT4 as they relate to incremental changes in neurodevelopmental outcomes. More specifically, the EPA only used studies that had sufficient data to show a quantitative relationship between maternal fT4 and a neurodevelopmental outcome. The EPA acknowledges that by not giving any weight to the studies that did not show a quantitative relationship between fT4 and neurodevelopmental outcomes, the Agency may be overestimating the dose of perchlorate that may be associated with adverse neurodevelopmental outcomes. This is a health protective decision that adds to the margin of safety.

Ultimately, the EPA developed a dose-response function that estimates incremental changes in a neurodevelopmental endpoint based on a given change in thyroid hormone concentration (fT4), which could be linked to a given dose of perchlorate using the BBDR model.

The specifics of this "methodologic approach to reviewing the literature" follow. First, the EPA identified and screened the available 71 epidemiological studies, which potentially pertained to altered maternal thyroid hormone levels and offspring neurodevelopment to identify candidates based on the following criteria:

- compatible with the sensitive life stages identified by the NRC and SAB;
- continuous measure of thyroid hormone values (versus categorical values);
- low risk of bias based on analysis using the National Toxicology Program's Office of Health Assessment and Translation (OHAT) Risk of Bias (ROB) tool score; and
- access to underlying data.

Second, using these screening steps, the EPA categorized all 71 studies into three groups. One group consisted of studies that were not compatible[6] with extending the BBDR model (40 studies). Another group consisted of papers that were relevant to the pertinent life stages but did not have data from which a dose-response analysis could be conducted (15 studies). This includes studies that compared differences between groups, for example studies of offspring of mothers with hypothyroxinemia versus offspring of mothers without hypothyroxinemia. Consequently, these studies may have provided insight into the maternal thyroid hormone and offspring neurodevelopment relationship but did not have enough information to develop a continuous dose-response function. The last group of papers had data that may inform a dose-response function (16 studies). This last group of papers included publications that may have had categorical analyses but also presented data that assessed fT4 as a continuous variable and the outcome of interest. In most instances, the continuous fT4 variable encompassed the full range for fT4 and not just the hypothyroxinemic range. After excluding one paper due to a high risk of bias (Kastakina et al., 2006) 15 papers remained that potentially had dose-response data between a continuous measure of fT4 and various neurodevelopmental outcomes describing cognition,

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[6] For example, if the study evaluated the impact of only neonatal thyroid hormones (i.e., at a potentially sensitive life stage), it cannot be used because the BBDR model is specific to early pregnancy. Further, if the study evaluates a population with an existing disease (i.e., hypothyroidism) that may have a different response to perchlorate compared to the euthyroid population, it was not considered compatible with BBDR model results. Additionally, if the study does not include information on T4 or fT4, it does not assist in understanding the implications of the BBDR modeling results. Another reason for exclusion at this stage include that the study does not have a population with an exposure window (i.e., when the thyroid hormone measurements are taken) that overlaps with the outputs for the BBDR model. Specifically, the study should evaluate thyroid hormone levels in pregnant mothers between conception and gestational week 16. The neurodevelopmental outcomes could be measured at any life stage.

behavior and other outcomes. The EPA notes that by selecting the papers that potentially had dose response data the Agency is deviating from the systematic weight of evidence review approach to identify those studies that the SAB recommended we examine to derive the MCLG.

Third, from these 15 papers five were selected for dose response assessment - four related to cognition[ADDIN EN.CITE ADDIN EN.CITE.DATA] and one related to behavior [ADDIN EN.CITE <EndNote><Cite><Author>Endendijk</Author><Year>2017</Year><RecNum>1915</RecNum><DisplayText>(Endendijk, Wijnen, Pop, & van Baar, 2017)</DisplayText><record><rec-number>1915</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1503500102">1915</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Endendijk, J.J.</author><author>Wijnen, H.A.</author><author>Pop, V.J.</author><author>van Baar, A.L.</author></authors></contributors><titles><title>Maternal thyroid hormone trajectories during pregnancy and child behavioral problems</title><secondary-title>Horm Behav</secondary-title></titles><periodical><full-title>Horm Behav</full-title></periodical><pages>84-92</pages><volume>94</volume><dates><year>2017</year></dates><urls></urls></record></Cite></EndNote>]. The other ten papers were excluded for a variety of reasons including updated analyses being presented in a different paper for which dose-response analysis was being conducted, lack of all the data needed to complete a dose-response assessment (e.g., dose-response results were presented as "per standard deviation of fT4" but the standard deviation needed to fully interpret the results for a continuous function was not presented in the paper, statistical methods presented in the paper were insufficient to allow for the derivation of a concentration response function), or a lack of a relationship between maternal fT4 as a continuous variable and the outcome of interest evaluated in the paper. For example, Noten et al., (2015) found a relationship between maternal hypothyroxinemia and offspring arithmetic test performance. However, maternal fT4 as a continuous variable across the entire fT4 range was not associated with arithmetic test performance. Given this null finding, as well as the lack of published literature evaluating maternal fT4 as a continuous variable and arithmetic test performance, it would be difficult for the Agency to justify setting an MCLG based on changes in this endpoint.

As laid out for the peer reviewers, for each study that met the criteria identified above for dose-response modeling, a relationship between maternal thyroid hormone levels (specifically fT4) and offspring neurodevelopment was derived (see USEPA, 2018b). These relationships were either presented in the original published paper or derived by the EPA through either the digitization of figures or through re-analysis of data provided by the study authors. The EPA used the upper effect estimate (the upper bound of the 95th percent confidence interval) from each study to assure consideration of the populations likely to be at greater risk from the dose of perchlorate associated with a given change in fT4.

Table III-2 provides a summary of the changes in fT4 predicted to produce a 1, 2, and 3 percent decrease in any given neurodevelopmental effect and corresponding perchlorate doses. The choice of 1, 2, and 3% is based on the analyses for IQ, Mental Development Index (MDI), and Psychomotor Development Index (PDI). Specifically, a 1%, 2%, or 3% change from the standardized mean for each test (i.e., 100 points) equates to a 1, 2, or 3 point change, respectively. The analyses for anxiety/depression score and SD of reaction time are based on a 1%, 2%, or 3% change from the study mean of each measure, which for anxiety/depression is 0.01, 0.02, or 0.03 points, respectively, and for reaction time is 2.7, 5.4, and 8.1 milliseconds (study mean SD of reaction time = 270 ms), respectively (Endendijk et al., 2017; Finken et al., 2013).

These results provide the potential impacts of perchlorate on maternal fT4 (as predicted by the BBDR model) and subsequent neurodevelopmental impacts (derived from the epidemiologic literature[7]).

[7] For a more complete description of all the studies evaluated the reader is directed to Sections 5 and 6 of the MCLG Approaches Report. For a discussion on the uncertainties related to the approach the reader is directed specifically to section 6.5.

Table III-2. Estimated Dose of Perchlorate per 1, 2, and 3 Percent Decrease[a] in Neurodevelopment for the Population of Low-Iodine Intake Women of Reproductive Age Based on Upper Effect Estimates at the 10th Percentile fT4 Level[b]

Study	Endpoint	Dose-Response Function	β (95% CI)	ΔfT4 in pmol/L Associated with a 1% to 3% Decrease in Endpoint (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 µg/day)[a,b,c]			Dose of Perchlorate per 1% to 3% Decrease in Endpoint (µg/kg/day)[a,b,c]		
				1%	2%	3%	1%	2%	3%
Korevaar et al. (2016) Quadratic	IQ	$\Delta IQ = (\beta_1 \times lnfT4_2 + \beta_2 \times ln(fT4_2)^2) - (\beta_1 \times lnfT4_1 + \beta_2 \times ln(fT4_1)^2)$	β1 = 33.8 (9.8, 57.8) β2 = -6.2 (-10.6, -1.9)	-0.13 (1.9%)	-0.25 (3.8%)	-0.38 (5.7%)	1.9	3.9	6.1
Korevaar et al. (2016) EPA independent analysis	IQ	$\Delta IQ = (\beta_1 \times \ln(fT4_2)) - (\beta_1 \times \ln(fT4_1))$	17.26 (3.77, 30.75)	-0.21 (3.1%)	-0.41 (6.2%)	-0.61 (9.2%)	3.1	6.7	10.8
Pop et al. (2003)	MDI	$\Delta MDI = \beta \times \Delta fT4$	6.3 (1.92, 10.6)	-0.09 (1.0%)	-0.19 (2.8%)	-0.28 (4.2%)	1.3	2.8	4.3
Pop et al. (2003)	PDI	$\Delta PDI = \beta \times \Delta fT4$	8.4 (4.0, 12.8)	-0.08 (0.9%)	-0.16 (2.4%)	-0.23 (3.5%)	1.1	2.3	3.5
Pop et al. (1999)	PDI	$\Delta PDI = \beta \times \Delta fT4$	8.5 (0.01, 17.0)	-0.06 (0.6%)	-0.12 (1.8%)	-0.18 (2.6%)	0.8	1.7	2.6
Endendijk et al. (2017)	Anxiety/ depression score	$\Delta AD = \left(\frac{1}{\beta * fT4_2}\right) - \left(\frac{1}{\beta * fT4_1}\right)$	0.12 (0.11, 0.13)	-0.03 (0.45%)	-0.08 (1.2%)	-0.12 (1.9%)	0.4	1.1	1.8
Finken et al. (2013)	SD of reaction time	ΔSD Reaction Time (ms) = β × Δ fT4	-4.9 (-9.5, -0.2)	-0.28 (4.2%)	-0.57 (8.5%)	-0.85[d] (12.7%)	4.4	9.8	16.5[d]

Study	Endpoint	Dose-Response Function	β (95% CI)	ΔfT4 in pmol/L Associated with a 1% to 3% Decrease in Endpoint (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 μg/day)[a,b,c]			Dose of Perchlorate per 1% to 3% Decrease in Endpoint (μg/kg/day)[a,b,c]		
				1%	2%	3%	1%	2%	3%

[a]. The analyses for IQ, Mental Development Index (MDI), and Psychomotor Development Index (PDI) are based on a 1%, 2%, or 3% change from the standardized mean for each test (i.e., 100 points), which equates to a 1, 2, or 3 point change, respectively. The analyses for anxiety/depression score and SD of reaction time are based on a 1%, 2%, or 3% change from the study mean of each measure, which for anxiety/depression is 0.01, 0.02, or 0.03 points, respectively, and for reaction time is 2.7, 5.4, and 8.1 milliseconds (study mean SD of reaction time = 270 ms), respectively.
[b]. This is based on the regression analysis for the range of fT4 data within each study using the upper beta estimates from the 95% CI. These results are for the low-iodide intake population of 75 μg/day. In all functions, fT4 is in units of pmol/L.
[c]. The BBDR model with a pTSH of 0.398 was used for these analyses.
[d]. The value which results in a 3% change in the standard deviation of reaction time falls between 16 and 17 μg/kg/day. Because data was not available on the changes of fT4 at doses between 16 and 17 μg/kg/day perchlorate, the EPA took the midpoint of the range of values for the change in fT4 at 16 and 17 μg/kg//day and assumed the dose of perchlorate associated with this change was the midpoint between 16 and 17 μg/kg/day.

H. Identifying a Point of Departure for Developing the MCLG

From the seven analyses presented in ~~this table~~Table III-2 above, the EPA chose to use its independent analysis of the Korevaar et al., (2016) data (comprising of 3,600 useable mother/child data pairs) as the basis for calculating the point of departure (POD) for the MCLG. There are three reasons for this selection: 1) there is sufficient quantitative data to derive a health impact function for the sensitive population of interest; 2) the analysis adjusts for an appropriate set of confounders, and 3) the neurodevelopmental endpoint – intelligence quotient (IQ) – is more straightforward to interpret because there is more national and cross-national data available (more on the selection of this endpoint below). The other studies presented in Table III-2 do not provide one or more of these features (USEPA, 2018b).

The five identified papers evaluated a variety of endpoints with Korevaar et al., (2016) evaluating IQ, Pop, Kuijpens, et al., (1999) and Pop, Brouwers, et al., (2003) using the Bayley Scale to evaluate PDI and MDI, Finken, van Eijsden, Loomans, Vrijkotte, and Rotteveel (2013) evaluating the SD of reaction time, and Endendijk, Wijnen, Pop, and van Baar (2017) evaluating anxiety/depression scores using the Child Behavioral Check List (CBCL). The SD of reaction time from Finken et al., (2013) was not well-received by the peer reviewers (External Peer Review for U.S. EPA, 2018) because it is difficult to ascertain the true implications of a change in the SD of reaction time. The Endendijk et al., (2017) study was identified after the peer review so no feedback was given on the appropriateness of the endpoint; however, the anxiety/depression raw score is not an intuitively interpretable endpoint. Further, neither the Endendijk et al., (2017) nor the Finken et al., (2013) analyses had functions for the sensitive life stage (i.e., their analyses were based on the full range of fT4 levels and did not concentrate on the impacts of low-end fT4 levels). For these reasons, the Endendijk et al., (2017) and Finken et al., (2013) papers were not selected for further evaluation.

The Korevaar et al., (2016) original and independent analyses are preferable compared to the Pop, Kuijpens, et al., (1999) and Pop, Brouwers, et al., (2003) studies because neither function derived from the Pop et al., studies was adjusted for confounders. Additionally, both

Pop et al., papers have an N < 50 compared to the Korevaar et al., analyses, which have an N of greater than 3,600.[8]

Although the original Korevaar et al., (2016) analysis was the most rigorous analysis available in the literature to date, the Korevaar et al., (2016) EPA reanalysis was chosen over the original analysis because it included modifications to the analysis at the suggestion of the peer review panel. The revised analysis controls for a more parsimonious set of confounders (e.g., previously included variables such as infant gender, maternal parity, birthweight, mother's body mass index (BMI), and gestational age at blood draw that are not related to both the exposure and the outcome were excluded), thus decreasing the chances of overfitting the estimation of the association between maternal fT4 and child IQ. The EPA was prompted to revisit the original Korevaar et al., (2016) model because of the feedback received during the peer review of the MCLG Approaches Report. Specifically, a member of the peer-review panel expressed the following suggestion:

> *Korevaar et al., [2016] controlled for instrumental variables (e.g. gestational week at fT4 measurement) as well as variables that are consequences of altered fT4 (e.g. maternal BMI), which may have biased estimates. This study also assumed a log-linear relation between fT4 and the outcome but it is unclear whether the data fit this functional form better than a linear form. Reanalysis of*

[8] The original Korevaar et al. (2016) analysis included 3,839 mother/child pairs. The EPA reanalysis of the Korevaar et al. (2016) data had a slightly lower N of 3,609 due to the exclusion of subjects with imputed values for maternal fT4.

the data performed by EPA should not include the variables noted above, which may have driven measures of association towards the null, and should investigate the most appropriate functional form to inform decisions about transformation of fT4 values (External Peer Reviewers for U.S. EPA, 2018, pp. 61–62).

The EPA responded to this suggestion by developing a causal model for the effect of maternal fT4 on child IQ to identify the minimum set of confounding variables, testing the proper functional form of the relationship between maternal fT4 and child IQ in the Korevaar et al., (2016) data, and making decisions about data quality and influential data points in the analysis. That is, the EPA determined that there were values of the independent variable of interest, fT4, in the original analysis that were imputed using multiple imputations. This could have impacted the effect estimate of the independent variable of interest with data that were not directly measured. The EPA reanalysis excludes these non-measured values. Subsequently, the EPA selected the Korevaar et al., (2016) reanalysis as the most appropriate function from which to assess the relationship between fT4 and IQ [9].

As indicated above, the EPA has utilized a health protective approach to this analysis consistent with the SDWA definition of the MCLG. The peer reviewers commented that this approach was fit-for-purpose. In particular, the Agency assumed it could estimate risk reductions based on evidence of a quantifiable relationship between thyroid hormone changes and

[9] A more complete description of the EPA independent analysis of the Korevaar et al. (2016) data can be found in Section 6.3.2 of the MCLG Approaches Report.

neurodevelopmental outcomes. The existence of a quantifiable relationship between thyroid hormone changes and neurodevelopmental outcomes has strong support from the literature on the subject; however, not every study identified an association between maternal fT4 and the specified outcome of interest, and the state of the science on this relationship is constantly evolving. As explained earlier, the results of the EPA's dose-response literature review identified 31 studies that evaluated the association between maternal thyroid hormone levels and offspring neurodevelopment, with neurodevelopment defined using a variety of endpoints related to cognition, behavior, and other outcomes such as autism. Among these studies, only 16 were deemed to potentially possess information that could inform a dose-response relationship. The other 15 only presented data on categorical analyses assessing the impact of maternal hypothyroxinemia on the neurodevelopmental outcomes of interest. Therefore, because the data presented was only a comparison of two groups, there was not information that could be used to inform a dose-response function.

~~Furthermore,~~ Of the 16 studies that potentially had data to inform a dose-response function, 10 evaluated cognition using a variety of tests including various IQ tests (three papers; Ghassabian et al., 2014; Korevaar et al., 2016; Moleti et al., 2016), Bayley Scales of Infant Development (two papers; Pop et al., 1999; Pop et al., 2003), and other validated tests associated with child cognition such as expressive language delay or test performance (five papers; Finken et al., 2013; Henrichs et al., 2010; Kastakina et al., 2006; Noten et al., 2015; Oken et al., 2009). Six of these papers found a statistically significant relationship between maternal fT4, as a continuous variable, and offspring cognitive outcome (Korevaar et al., 2016; Pop et al., 1999; Pop et al., 2003; Finken et al., 2013; Henrichs et al., 2010, Kastakina et al., 2006). However, there were studies where maternal fT4 as a continuous variable was not significantly associated with the outcome of interest. For example, in Ghassabian et al., (2014) the authors found maternal hypothyroxinemia to be associated with an average of a 4.3-point reduction in IQ in their offspring compared to offspring of non-hypothyroxinemic mothers. Nevertheless, when assessing the relationship between the continuous measure of maternal fT4 as a continuous variable (across the entire range of fT4 levels) and child IQ, the authors did not find a significant relationship. Additionally, Moleti et al., (2016) found the relationship between maternal fT4 and child IQ to be consistently inversely associated with IQ scores, but their assessment failed to reach statistical significance. This study included fewer than 60 study participants and was considered by the authors to be a pilot assessment.

In addition to the cognitive effects assessed and modeled, the EPA identified four papers that assessed maternal fT4 status and behavioral outcomes (Endendijk et al., 2017; Ghassabian et al., 2011; Modesto et al., 2015; Oostenbroek et al., 2017), one paper that assessed maternal fT4 status and autism (Roman et al., 2013) and one paper that evaluated odds of a schizophrenia diagnosis as associated with maternal thyroid hormone status (Gyllenberg et al., 2016). From this group of papers, the majority of papers found an association either between maternal hypothyroxinemia or maternal fT4 as a continuous variable and the outcome of interest (Endendijk et al., 2017; Modesto et al., 2015; Oostenbroek et al., 2017; Roman et al., 2013;

Gyllenberg et al., 2016). However, this was not always the case as exemplified by Ghassabian et al., (2011) and Gyllenberg et al., (2016). Although Endendijk et al., (2017) found maternal fT4 to have a significant adverse impact on anxiety/depression using the Child Behavioral Check List (CBCL), Ghassabian et al., (2011) did not find any association between maternal thyroid hormone status and offspring score on various components of the CBCL. Additionally, Gyllenberg et al., (2016) found maternal hypothyroxinemia during early to mid-gestation was associated with 70% increased odds of schizophrenia diagnosis in offspring of hypothyroxinemic mothers compared to the offspring of non-hypothyroxinemic mothers. Gyllenberg et al., (2016) also found an association with odds of schizophrenia diagnosis using conditional logistic regression when assessing fT4 as a continuous variable across the entire fT4 range (i.e., not just the hypothyroxinemic range); however, this relationship was attenuated after controlling for smoking.

Not every paper the EPA located in its literature review found a statistically significant association between maternal fT4 as a continuous variable (i.e., the initially identified 16 studies identified as potentially useful to inform a dose-response function) and the neurodevelopmental outcome of interest. However, many studies located in the EPA literature review, several meta-analyses ([HYPERLINK \l "_ENREF_47" \o "Fan, 2016 #307"]; Thompson et al., 2018 and [HYPERLINK \l "_ENREF_187" \o "Wang, 2016 #327"]), the American Thyroid Association (Alexander et al., 2017) and the U.S. EPA's SAB (2013) have concluded there is a relationship between maternal hypothyroxinemia and various neurodevelopmental outcomes. The relationship between maternal fT4 levels and neurodevelopmental outcomes appears strongest in the hypothyroxinemic range, and when looking at the entire range of fT4 as a continuous variable (as opposed to a categorical cut off), the significant relationship between the two variables may dissipate. Therefore, the EPA has concentrated on the neurodevelopmental impacts of changes in fT4 in the lower range of fT4 from the Korevaar et al., (2016) data. In an attempt to minimize uncertainty, the EPA reanalyzed the data collected by Korevaar et al., (2016) using a spline function that estimates a coefficient specifically for the low range of the fT4 data.

There are a variety of neurodevelopmental endpoints used to examine behavior and cognition in children (e.g., intelligence quotient (IQ), motor skills, vocabulary and language development, stimulus responsiveness, etc.). The EPA selected IQ decrements because this was the endpoint evaluated in the Korevaar et al., (2016) study. The EPA determined that the Korevaar study was the most rigorous analysis that examined the relationship between decreased thyroid hormones and neurodevelopmental effects. As such, in the derivation of the MCLG, IQ is a surrogate for a suite of potential neurodevelopmental effects that might occur to the offspring of hypothyroxinemic and iodine deficient mothers.

There are several different tests that are widely used to measure IQ in children, including the Stanford-Binet and the Wechsler Intelligence Scale for Children (WISC) (Sternberg et al., 2001). Each of these tests is intended to assess a child's global functioning and uses a numerical IQ point scale (Beres et al., 2000). IQ scores are standardized by age and sex group with a mean score of 100 points and a standard deviation of 15 (Beres et al., 2000). Although the specific tasks differ by test, all IQ tests contain a number of tasks to assess diverse skills (Sternberg et al., 2001). For example, the WISC test evaluates full-scale IQ using a combination of verbal and performance scales (verbal IQ and performance IQ may also be assessed separately) (Beres et al., 2000). The verbal scale includes tasks such as arithmetic, vocabulary, and comprehension, while the performance scale includes tasks such as picture completion, block design, and object assembly (Beres et al., 2000). The WISC was standardized using a sample of 2200 U.S. children aged 6 to 16 years old (Seashore et al., 1950). It has been well validated and has demonstrated high reliability, with a reliability coefficient of 0.96 observed across age groups (Beres et al., 2000).

Associations have been found between IQ scores and both educational achievement and attainment, though observed correlations vary widely. In a review of the literature, Sternberg et al. (2001) suggest that IQ scores explain approximately 25% of the variance in academic achievement. Evidence also suggests that IQ is linked to career outcomes and job performance, with observed correlations ranging from approximately 0.2 to 0.6 (Sternberg et al., 2001). Research suggests that children's rearing environment, including parental education, while growing up may increase IQ scores in adolescence by several points (e.g., Kendler et al., 2015).

IQ scores have been used to help diagnose disorders such as intellectual disability and to identify children for placement into specialized learning programs (Beres et al., 2000). For example, in the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-V) IQ scores are used in an individual's comprehensive assessment to determine intellectual disability, which pairs standardized testing of intelligence with a clinical assessment of adaptive functioning. Intellectual disability is considered for individuals with an IQ score of about 70 or below (American Psychiatric Association, 2013).

The EPA uses a variety of science policy approaches to select points of departure for developing regulatory values. For instance, in noncancer risk assessment the EPA often uses a percentage change in value ~~in noncancer risk assessment.~~. When assessing toxicological data, a 10 percent extra risk (for discrete data), or a 1 standard deviation (i.e., 15 IQ points) change from the mean (for continuous data) is often used (USEPA, 2012). A smaller response to inform a POD has been applied when using epidemiological literature because there is an inherently more direct relationship between the study results and the exposure context and health endpoint. Given the difficulty in identifying a response below which no adverse impact occurs when considering a continuous outcome in the human population, the EPA looked to its Benchmark Dose Guidance (2012) for insight regarding a starting point. Specifically, "[a] BMR of 1% has typically been used for quantal human data from epidemiology studies" (p. 21, USEPA, 2012).

For the specific context of setting an MCLG for perchlorate, the EPA made a policy decision to evaluate the level of perchlorate in water associated with a 1 percent decrease, a 2 percent decrease, and a 3 percent decrease in population IQ. The EPA selected IQ as a surrogate for neurodevelopmental effects based upon its evaluation of the epidemiologic literature describe above. The need to utilize the best available peer reviewed data to inform scientific assumptions and policy choices to meet the statutory requirements associated with developing an MCLG under the SDWA highlights the challenges associated with regulating chemicals for which potential effects are indirect, and scientific data do not address all uncertainties. ~~Sometimes as in this case,~~ The Agency must make a policy decision ~~as to what effect is adverse when~~informed by science ~~does~~, consistent with statutory requirements even in situations where the data do not provide ~~a~~ clear ~~threshold~~choices. In this case, the EPA made a policy decision to use a 2 IQ point decrement to develop the proposed MCLG for perchlorate. By selecting this approach, the EPA is not establishing a precedent for future Agency actions on other contaminants for which there is concern about potential thyroid effects, either under the SDWA or other statutory frameworks.

Applying these response rates to the results from the reanalysis of Korevaar et al., (2016), results in a POD dose of 3.1 μg/kg/day for a 1 percent decrease in the population's IQ, a POD dose of 6.7 μg/kg/day for a 2 percent decrease in the population's IQ, and a POD dose of 10.8 μg/kg/day for a 3 percent decrease in the population's IQ. These PODs associated with a 1, 2, or 3 percent decrease from the standardized mean IQ are calculated for the most sensitive population. Specifically, the POD is designed to provide an adequate margin of safety for the fetuses of mothers with fT4 at the 10^{th} percentile of a population with iodine intake of 75 μg/day and a TSH feedback loop that is less than 60% as effective as individuals with median TSH feedback loop efficacy. That is, the analysis is designed to protect the population of fetuses of mothers with suboptimal thyroid functioning. For these reasons, and for the methodological reasons described previously, the EPA believes that the selection of these parameters and this point of departure assures no known or anticipated adverse effects on the health of the most sensitive population and allows for an adequate margin of safety.

I. Translate PODs to RfDs

When deriving an RfD the EPA evaluates whether to apply uncertainty/variability factors to account for heterogeneity of effect in the target population and data gaps (USEPA, 2002). As presented in *A Review of the RfD & RfC Processes* (USEPA, 2002) the EPA considers the following uncertainty factors: inter-individual variability, interspecies uncertainty, extrapolating from subchronic to chronic exposure, extrapolating from a lowest-observed adverse effect level (LOAEL) rather than from a no-observed-adverse-effect-level (NOAEL), and an incomplete database. The factors are intended to account for: 1) variation in susceptibility among the members of the human population (i.e., inter-individual or intraspecies variability); 2) uncertainty in extrapolating animal data to humans (i.e., interspecies uncertainty); 3) uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); 4) uncertainty in extrapolating from a LOAEL rather than from a NOAEL; and 5) uncertainty associated with extrapolation when the database is incomplete. (U.S. EPA, 2011b) The EPA has considered each of these factors in deriving an RfD to inform an MCLG for perchlorate.

The EPA considered variation and uncertainty in the relationship between exposure and response among the members of the human population (i.e., uncertainty factor (UF) for within-human variability/ inter-individual variability, UF_H). For this analysis a UF of 3 is used. The approach taken to derive the RfD attempts to address variability between the general population and the sensitive population. Specifically, the EPA was able to modify the strength of the TSH feedback loop and iodine intake levels in the BBDR model and concentrate on the dose-response relationship between lower level (as opposed to median level) fT4 and neurodevelopmental outcomes. However, there is still uncertainty in the relationship between perchlorate exposure and subsequent neurodevelopmental outcomes[10]. There are very few toxicokinetic calibration data available for the perchlorate to thyroid hormone relationship described in the BBDR model. On the toxicodynamic side of the BBDR model, aspects such as competitive inhibition at the NIS, depletion of iodide stores under different iodine intake levels and physiological states, and the ability of the TSH feedback loop to compensate for perturbations in thyroid function each have their own uncertain features. There are also uncertainties linking maternal fT4 levels to offspring IQ. These uncertainties include the population for which dose-response information is available (i.e., no study is U.S. based), a lack of study information on the iodine intake status for the population for which the dose-response information is available, uncertainties around the methods used to assess maternal fT4 measurement during pregnancy, and uncertainties related to the true distribution of fT4 for a given iodine intake.

Further, as discussed in section III.C. of this notice the EPA believes that protecting the

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[10] For a more complete discussion on the uncertainties in the analysis the reader is directed to Sections 3.5 and 6.5 of the MCLG Approaches Report.

fetus of a hypothyroxinemic woman will protect other identified sensitive life stages. However, there is some uncertainty due to the lack of information linking incremental changes in infant thyroid hormone levels to adverse neuorodevelopmental outcomes. In addition, this analysis is assuming that protecting a first trimester fetus from alterations in maternal fT4 will protect the fetus throughout pregnancy. This is based on epidemiologic evidence that shows the relationship between first trimester maternal fT4 and neurodevelopmental outcomes. This is potentially because before mid-gestation, the mother is the only source of thyroid hormone for the fetus (Morreale de Escobar et al., 2004). Therefore, when evaluating maternal fT4 as associated with neurodevelopmental outcomes it is critical to understand the first-trimester levels. Later in gestation, when the fetal thyroid begins secreting thyroid hormones, maternal fT4 may no longer be a good surrogate for the thyroid hormone levels available to the fetus. Given that the fetal thyroid has had little time to develop, its iodine storage is much less than that of an adult, hence there may be more sensitivity to short-term fluctuations in iodine availability and uptake that may have little impact on maternal levels. Therefore, there is some uncertainty about the impact perchlorate may have on the fetal thyroid gland, and subsequent neurodevelopmental impacts, in later trimesters of pregnancy. The immature fetal HPT axis has very limited capacity to increase output of thyroid hormones (Savin, Cvejić, Nedić, & Radosavljević, 2003; van Den Hove, Beckers, Devlieger, De Zegher, & De Nayer, 1999), so the fetal HPT may not be able to adjust output in the face of reduced maternal fT4 supply and perchlorate exposure. Therefore, as described above, the EPA selected an intraspecies UF of 3 to account for the uncertainties in modeling the impacts of perchlorate ingestion on the thyroid hormone levels for pregnant mothers with low iodide intake, and the uncertainties in predicting the neurodevelopmental effects of these thyroid hormone changes on their children.

The EPA considered but did not derive a Data-Dependent Extrapolation Factor (DDEF) for this analysis. As described above, the UFs are applied based on the uncertainties in the perchlorate to thyroid hormone and thyroid hormone to neurodevelopment relationship[11]. As noted above, the Agency has opted to apply a UF of 3 to the POD, which adds an adequate margin of safety to the MCLG derivation. Section 4.4.5.3 (p 4-42) of *A Review of the RfD & RfC Processes* recommends reducing the intraspecies UF from a default of 10 "only if data are sufficiently representative of the exposure/dose-response data for the most susceptible subpopulation(s)" (p. xviii, USEPA, 2002).The EPA selected a UF of 3 instead of the full 10 because the modeled groups within the population that are identified as likely to be at greater risk to perchlorate in drinking water (i.e., the fetus of the iodide deficient pregnant mother) and has selected model parameters to account for the most sensitive individuals in that group (i.e., muted TSH feedback, low fT4 values, low-iodine intake).

Below we list the other uncertainty factors added and the justification.

- Uncertainty in extrapolating animal data to humans (i.e., interspecies uncertainty) (uncertainty factor, animal-to-human, UF_A). For this analysis an UF of 1 is used because this

[11]As explained in U.S. EPA, 2014 "UFs incorporate both extrapolation components that address variability (heterogeneity between species or within a population) and components that address uncertainty (i.e., lack of knowledge)…whereas DDEFs focus on variability" (p. 7, US EPA, 2014).

factor is not applicable since animal studies were not used to develop the BBDR model nor were they used to relate alterations in maternal fT4 to IQ.

- Uncertainty in extrapolating data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure, UF_S). An uncertainty factor of 1 is used. Extrapolating from subchronic to chronic exposures did not occur as the BBDR model was designed to assess long-term steady-state conditions in the non-pregnant woman and week-to-week variation in pregnancy, rather than short-term (hour-to-hour or day-to-day) fluctuations.
- Uncertainty in extrapolating from a LOAEL rather than from a NOAEL (uncertainty factor, LOAEL-to-NOAEL, UF_L). A more sophisticated BBDR modeling approach, coupled with extrapolation to changes in IQ using linear regression, was used to determine a POD that would not be expected to represent an adverse effect. Subsequently an uncertainty factor of 1 is used. LOAELs and NOAELs were not identified or used in this approach.
- Uncertainty factor for database deficiency to address the potential for deriving an inadequately protective RfD in the instance where the available database provides an incomplete characterization of the chemical's toxicity (database deficiency, $UF_{D;}$ USEPA, 2002). An uncertainty factor of 1 is used as "[t]he mode of action of perchlorate toxicity is well understood" (SAB for the U.S. EPA, 2013, p. 2).
- The product of all the uncertainty factors (UF_H) is 3 (3 x 1 x 1 x 1 x 1).

Below we generate RfD's for each of the points of departure.

Using the POD of 6.7 µg/kg/day based on a 2 percent decrease in the population standardized mean IQ from the EPA's independent analysis of the Korevaar et al., (2016) data, the EPA can derive a RfD by incorporating the UF_H, which results in the following:

$$RfD = \frac{POD}{UF_H} = \frac{6.7}{3} = 2.2\ \frac{\mu g/kg}{day}$$

Using an alternative POD of 3.1 µg/kg/day based on a 1 percent decrease in the population standardized mean IQ from the EPA's independent analysis of the Korevaar et al., (2016) data, the EPA can derive an RfD by incorporating the UF_H. This results in the following:

$$RfD = \frac{POD}{UF_H} = \frac{3.1}{3} = 1.0\ \frac{\mu g/kg}{day}$$

Using an alternative POD of 10.8 µg/kg/day based on a 3 percent decrease in the population standardized mean IQ from the EPA's independent analysis of the Korevaar et al., (2016) data, the EPA can derive an RfD by incorporating the UF_H. This results in the following:

$$RfD = \frac{POD}{UF_H} = \frac{10.8}{3} = 3.6\ \frac{\mu g/kg}{day}$$

J. Translate RfD into an MCLG

To translate the RfD (µg/kg/day) to a concentration in drinking water (µg/L), the EPA used the following equation:

$$W\ \left(\frac{\mu g}{L}\right) = \frac{RfD}{DWI} \times RSC_w$$

where:

W = drinking water concentration of perchlorate in micrograms per liter (µg/L);

RfD = reference dose (1.03 μg/kg/day for a 1 percent decrease in IQ, 2.23 μg/kg/day for a 2 percent decrease in IQ, or 3.6 μg/kg/day for a 3 percent decrease in IQ);

DWI = bodyweight-adjusted drinking water ingestion rate (L/kg/day); and

RSC_w = relative source contribution of drinking water to overall perchlorate exposure.

To calculate the MCLGs, the EPA selected the 90th percentile body-weight adjusted drinking water ingestion rate specific to women of childbearing age (i.e., non-pregnant, non-lactating, 15–44 years of age (0.032 L/kg/day). This decision is consistent with the analysis used in deriving an RSC, which was performed using food consumption information for a population of women of childbearing age from NHANES. The 90^{th} percentile is chosen to account for variability in drinking water ingestion rates, but also adds another layer of health protection for 90% of women (Table III-3).

The EPA did not use water intake data for pregnant women because the sample sizes were too small to be statistically stable. The use of the drinking water intake for 15-44 year old women is consistent with the analysis used in deriving an RSC_w (described below), which was performed using food consumption information for a population of women of childbearing age from NHANES. The EPA acknowledges there is a difference in the age range defining women of childbearing age used to develop the drinking water ingestion rate and that used to develop the RSC (20 – 44 years of age). The age range used to develop the RSC was based on the range of ages used to define women of childbearing age in developing the BBDR model. However, the

EPA's Exposure Factors Handbook (USEPA, 2011c) identifies drinking water ingestion rates for women 15-44 years of age as corresponding to women of childbearing age.

The age range used for women of childbearing age in the BBDR model fits within the age range used to develop the ingestion rates provided in the Exposure Factors Handbook. Thus, the Agency believes the difference in the age ranges will have minimal impact on the resulting MCLG analysis.

Table III-3. Consumers-Only Estimated Direct and Indirect Community Water Ingestion Rates from Kahn and Stralka (2008) (L/kg/day)

Female Population Categories	Sample Size	Mean	90th Percentile	95th Percentile
Pregnant	65	0.014[a]	0.033[a]	0.043[a]
Lactating	33	0.026[a]	0.054[a]	0.055[a]
Non-pregnant, non-lactating, 15 to 44 years of age	2,028	0.015	0.032	0.038

[a] The sample size does not meet minimum reporting requirements to make statistically reliable estimates as described in the *Third Report on Nutrition Monitoring in the United States*, 1994-1996 (FASEB/LSRO, 1995).

Individuals are exposed to perchlorate through ingestion of both food and drinking water (ATSDR 2008, Huber et al., 2011). In calculating the MCLGs, the EPA applies a relative source contribution (RSC) to the RfD to account for the percentage of the RfD remaining for drinking water after other sources of exposure to perchlorate have been considered. Thus, the RSC for drinking water is based on the following equation where "Food" is the perchlorate dose from food ingestion:

$$RSC = \frac{RfD - Food}{RfD} \times 100\%$$

To estimate the dose of perchlorate for women of childbearing age coming from food, the EPA implemented a data integration methodology that combined demographic variables, food consumption estimates, and perchlorate contamination estimates in food from multiple sources (USEPA, 2019c). These sources include:

- The NHANES data available from the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) including the What We Eat in America (WWEIA) 24-hour food diary data (CDC & NCHS, 2007, 2009, 2011); and
- The Food and Drug Administration's (FDA's) Total Diet Study (TDS) (U.S. Food and Drug Administration (FDA), 2015), which analyzes contaminants in about 280 kinds of food and beverages commonly consumed by the U.S. population.

The NHANES data provided individual food consumption profiles for female participants age 20-44 (the women of childbearing age range used for the BBDR model). The EPA matched TDS perchlorate concentrations with each food consumed by a participant and calculated each participant's daily perchlorate dose (µg/kg/day) from food using the participant's body weight. The EPA estimated each participant's perchlorate dose using both mean and 95th percentile perchlorate concentrations in food. The details of these assumptions are explained on page 5-5 of the Technical Support Document: Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water (USEPA 2019c). Specifically, the EPA calculated both the mean and the 95th percentile of the perchlorate levels in each food based on the 20 samples included in the TDS data. In order to estimate the 95th percentile from the 20 samples, the EPA used the second-highest test result for each food to represent the 95th percentile concentration. While simple, this method avoids the need to assume a distributional shape for the samples, and has been used in recent publications of TDS data for iodine [ADDIN EN.CITE <EndNote><Cite><Author>Carriquiry</Author><Year>2016</Year><RecNum>2008</RecNum><DisplayText>(Carriquiry et al., 2016)</DisplayText><record><rec-number>2008</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1530039524">2008</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Carriquiry, A. L. </author><author>Spungen, J. H.</author><author>Murphy, S. P.</author><author>Pehrsson, P. R.</author><author>Dwyer, J. T.</author><author>Juan, W.</author><author>Wirtz, M. S. </author></authors></contributors><titles><title>Variation in the iodine concentrations of foods: considerations for dietary assessment</title><secondary-title>The American Journal of Clinical Nutrition</secondary-title></titles><periodical><full-title>The American Journal of Clinical Nutrition</full-title></periodical><pages>877S–887S</pages><volume>104</volume><number>Suppl 3</number><dates><year>2016</year></dates><urls></urls></record></Cite></EndNote>]. The aforementioned method for identifying the 95th percentile concentration of perchlorate from food was selected over other, more "statistically based" methods for estimating percentiles as it avoids the need to assume a distributional shape for the samples. The EPA determined that it was more reliable to assume the empirically derived distribution as the basis for selecting the 95th

percentile (i.e., assuming the distribution was equal to the distribution of samples collected in the TDS), as opposed to forcing a distributional shape, such as normal or log-normal, onto the data that may not necessarily be appropriate. With the chosen method, we can at least be sure that the distributional shape is appropriate for the data at hand, whereas by choosing the alternative that assumes a distributional shape, in many instances we would not even be certain of that. The EPA used these individual bodyweight-adjusted perchlorate doses from food to calculate distributions of perchlorate dose from food for the population of women age 20-44.

Table III-4 presents the mean and selected percentiles of the distribution of perchlorate dose from food for women ages 20-44, for both mean and 95th percentile perchlorate concentrations in food based on the TDS. To calculate the RSC, the EPA selected the 90th percentile dose of perchlorate from food, assuming a scenario where the food contained the 95th percentile perchlorate concentration. This corresponds to a perchlorate dose for food of 0.45 μg/kg/day. The EPA chose to use the 90th percentile bodyweight-adjusted perchlorate consumption from food using the 95th percentile TDS results to estimate the perchlorate RSC from drinking water. The EPA believes this is the most appropriate value for perchlorate consumption from food to ensure the protection of potentially highly exposed individuals. Given the range of perchlorate concentrations in food, and that food is the only other exposure source being considered in the RSC analysis, the EPA believes it is sufficiently protective to estimate the MCLG for drinking water using the 90th percentile bodyweight-adjusted perchlorate consumption based on the 95th percentile perchlorate food concentrations in TDS. This assures that highly exposed individuals from this most sensitive population are considered in the evaluation of whether perchlorate is found at levels of health concern.

Table III-4. Perchlorate Dose from Food (μg/kg/day) in U.S. Women Ages 20-44 using the mean and 95th Percentile TDS Results[1]

Level of Bodyweight Adjusted Perchlorate Consumption from Population Distribution	Perchlorate Dose from Food (μg/kg/day)	
	Based on Mean Concentrations of Perchlorate in Food	Based on 95th Percentile Concentrations of Perchlorate in Food
Mean	0.09 – 0.12	0.23 – 0.24
50th Percentile	0.08 – 0.10	0.17 – 0.19
90th Percentile	0.18 – 0.21	**0.45**
99th Percentile	0.33 – 0.38	1.16 – 1.17

[1] Ranges are due to various approaches for handling values <level of detection. If no range is presented all approaches resulted in the same value.
Bolded value represents the selected value

The EPA used the drinking water intake and perchlorate dose from food to calculate MCLGs for the three RfD values. Table III-5 shows the RSC values for the three RfD values and the corresponding MCLGs calculated using the EPA's standard equation.

Table III-5. Estimates for RSC and MCLG by RfD

RfD[a] (μg/kg/day)	RSC_W[b] (percent)	DWI (L/kg/day)	MCLG[c] (μg/L)
1.0	56%	0.032	18
2.2	80%	0.032	56
3.6	80%[d]	0.032	90

a. The RfD values corresponding to protecting the fetus of a first trimester pregnant mother with low-iodine intake levels (i.e., 75 μg/kg/day), low fT4 levels (i.e., 10th percentile of a fT4 distribution for individuals with 75 μg/day iodine intake), and weak TSH feedback strength (i.e., TSH feedback is reduced to be approximately 60 percent less effective than for the median individual) from either a 1-point IQ loss ~~or a~~, 2-point IQ loss, or a 3-point IQ loss, respectively.

b. The EPA calculated RSC values based on the following equation given a Food intake of 0.45 µg/kg/day:

$$RSC = \frac{RfD - Food}{RfD} \times 100\%$$

c. The EPA calculated the MCLG values based on the following equation given the respective RfD and RSC values and the DWI:

$$W\left(\frac{\mu g}{L}\right) = \frac{RfD}{DWI} \times RSC_w$$

d. The calculated RSC value using the equation in footnote b is 88 percent. However, the EPA has opted to follow previously established recommendations which employs a ceiling of 80 percent for the RSC value (USEPA 2000d).

IV. Maximum Contaminant Level Goal and Alternatives

Section 1412(a)(3) of the SDWA requires the EPA to propose a maximum contaminant level goal (MCLG) simultaneously with the NPDWR. The MCLG is defined in Section 1412(b)(4)(A) as "the level at which no known or anticipated adverse effects on the health of persons occurs and which allows an adequate margin of safety." The EPA is proposing an MCLG of 56 µg/L based on the rationale and methodology described in Section III above. The derivation of the proposed MCLG uses a point of departure based upon a two percent decrease in IQ for offspring of hypothyroxinemic women of child bearing age have with low iodine intake. The EPA selected a 2 percent decrease in IQ for the proposed perchlorate MCLG because this represents a small change in IQ, well below one standard deviation for the subpopulation of interest.

As described in Section III, the EPA has selected model parameters and other factors for the derivation of the MCLG that are health protective, including the focus on the most sensitive life stage. The EPA believes that the selection of the combination of protective parameters and this point of departure assures no known or anticipated adverse effects on the health of the most sensitive subpopulation and allows for an adequate margin of safety. The EPA also acknowledges the uncertainties in the derivation of the proposed (and alternative) MCLGs. The EPA acknowledges in particular the challenge associated with selecting the decrement of IQ that represents an adverse effect at the population level and the uncertainties in predicting the dose of perchlorate that may result in a particular IQ decrement given the absence of robust human epidemiological data directly linking perchlorate exposure to IQ decrements. The Agency seeks comment on the alternative MCLG values of 18 μg/L and 90 μg/L, which the EPA derived using the methodology described in Section III based on a one percent and three percent decrease in IQ, respectively.

V. Maximum Contaminant Level and Alternatives

Under section 1412(b)(4)(B) of the SDWA, the EPA must establish a maximum contaminant level (MCL) as close to the MCLG as is feasible. The EPA evaluated available analytical methods to determine the lowest concentration at which perchlorate can be measured and evaluated the treatment technologies for perchlorate that have been examined under field conditions (USEPA 2018a, 2019b). The EPA determined that setting an MCL equal to the proposed MCLG of 56 μg/L is feasible given that the approved analytical method for perchlorate for UCMR 1 has a minimum reporting level (MRL) of 4 μg/L (USEPA 1999, 2000c) and that available treatment technologies can treat to concentrations well below 56 μg/L (USEPA, 2018c). Therefore, the EPA is proposing to set the MCL for perchlorate at 56 μg/L.

Because the EPA is taking comment on alternative MCLG values of 18 μg/L and 90 μg/L the Agency evaluated the feasibility of setting an MCL at these levels. The EPA determined that the proposed MCL of 56 μg/L is feasible, therefore a higher MCL alternative such as 90 μg/L is also feasible. The EPA has concluded that analytical methods are capable of measuring perchlorate at 18 μg/L and that treatment technologies have been demonstrated to achieve this level under field conditions (USEPA 2018a, 2019b). Therefore, the EPA is requesting comment on the feasibility of the proposed MCL of 56 μg/L as well as the feasibility of the alternative MCLs of 18 μg/L and 90 μg/L.

As the occurrence analysis in section VI demonstrates, there is infrequent occurrence of perchlorate at 18 μg/L, 56 μg/L, or 90 μg/L. Therefore, the EPA did not evaluate alternative MCL values greater than the corresponding MCLG values. The purpose for evaluating alternative MCL values is to determine whether there is an MCL at which benefits justify the costs of setting an MCL. Given infrequent occurrence, the majority of the costs associated with establishing an NPDWR for perchlorate are for administrative and initial monitoring activities (see section XI.B), which will not be significantly affected by MCL values greater than corresponding MCLG values.

When proposing an MCL, the EPA must publish, and seek public comment on, the health risk reduction and cost analyses (HRRCA) of each alternative MCL considered (SDWA Section 1412(b)(3)(C)(i)), including: the quantifiable and nonquantifiable health risk reduction benefits attributable to MCL compliance; the quantifiable and nonquantifiable health risk reduction benefits of reduced exposure to co-occurring contaminants attributable to MCL compliance; the quantifiable and nonquantifiable costs of MCL compliance; the incremental costs and benefits of each alternative MCL; the effects of the contaminant on the general population and sensitive subpopulations likely to be at greater risk of exposure; any adverse health risks posed by compliance; and other factors such as data quality and uncertainty. The EPA provides this information in section XII. The EPA must base its action on the best available, peer-reviewed science and supporting studies, taking into consideration the quality of the information and the uncertainties in the benefit-cost analysis (SDWA Section 1412(b)(3)). The following sections, as well as the health effects discussion in section III document the science and studies that the EPA relied upon to develop estimates of benefits and costs and understand the impact of uncertainty on the Agency's analysis.

VI. Occurrence

The UCMR 1 is the primary source of occurrence data the EPA relied on to estimate the number of water systems (and associated population) expected to be exposed at levels of perchlorate which could potentially exceed the proposed and alternative MCL levels. Since UCMR 1 data was first used to inform the Agency actions on the 2008 preliminary regulatory determination and the 2011 final regulatory determination, the Agency has modified its analysis of the UCMR 1 data set in response to concerns raised by stakeholders regarding the data quality and to represent current conditions at some States that have enacted perchlorate regulations since the UCMR 1 data was collected. Despite these updates, the EPA continues to rely on the UCMR

1 data because they are the best available data collected in accordance with accepted methods from a census of the large water systems (serving more than 10,000 people) and a statistically representative sample of small water systems that provides the best available, national assessment of perchlorate occurrence in drinking water.

In 1999, the EPA developed the first round of the UCMR program in accordance with SDWA requirements to provide national occurrence information on unregulated contaminants (USEPA, 1999, 2000b). The UCMR 1 required sampling from systems in all 50 States, the District of Columbia, four U.S. territories, and tribal lands in five EPA Regions including:

- all 3,097 large (serving more than 10,000 people) CWSs and NTNCWSs, which analyzed either four quarterly samples collected at 3-month intervals (surface water sources), or two samples collected 5 to 7 months apart (ground water sources); and
- a statistically representative selection of 800 small CWSs and NTNCWSs, which analyzed either four quarterly samples collected at 3-month intervals (surface water sources) or two samples collected 5 to 7 months apart (ground water sources).

Water systems submitted UCMR 1 sampling results to the EPA from 2001 until 2005. Water systems were required to analyze samples for 26 contaminants including perchlorate. The EPA established a minimum reporting level of 4 µg/L for perchlorate in the UCMR.

The EPA conducted a data quality review of the UCMR 1 data submitted by systems prior to analyzing the occurrence data for the 2011 perchlorate regulatory determination. The

UCMR 1 dataset used by the EPA included 34,331 samples with 637 measurements of perchlorate above the minimum reporting level from 3,865 systems.

In September of 2012, the EPA received a "Request for Correction" letter from the United States Chamber of Commerce regarding information and data (i.e., the occurrence of perchlorate in drinking water) used by the EPA in its 2011 determination to regulate perchlorate. The U.S. Chamber of Commerce letter stated that the EPA relied upon: 1) data that did not comply with data quality guidelines and 2) data that was not representative of current conditions.

In response[12] to the U.S. Chamber of Commerce, the EPA conducted a detailed assessment of the source water sample detections and determined that it was most appropriate to exclude the source water sample detections from the UCMR 1 perchlorate data set when those samples had appropriate follow-up entry point samples that were included in the UCMR 1 perchlorate data set. In contrast, any source water sample perchlorate detections for which no follow-up entry point sampling was conducted by PWSs were retained in the UCMR 1 perchlorate data set. As a result of the assessment, the EPA removed 199 source water samples (97 detections) that could be paired with a second follow-up sample located at the entry point to the distribution system. Following this convention, the resulting UCMR 1 data set contains 34,132 perchlorate samples from 3,865 systems with a total of 540 detections from 149 PWSs.

[12] See the EPA response letter at https://www.epa.gov/sites/production/files/2017-08/documents/12004-response_0.pdf

Table VI-1 shows sample distribution by system size category and measurement status. It also shows the number of entry points and systems where perchlorate measurements were reported. The entry point estimates differ from the system estimates because many water systems have more than one entry point. For example, a ground water system with two wells that has separate connections to the distribution system has two entry points.

In response to the U.S. Chamber of Commerce request, the EPA has also reassessed the UCMR 1 data in light of the adoption of regulatory limits in two states. Massachusetts promulgated a drinking water standard for perchlorate of 2 μg/L in 2006 [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"8DPpSrv3","properties":{"formattedCitation":"(MassDEP, 2006)","plainCitation":"(MassDEP, 2006)","noteIndex":0},"citationItems":[{"id":151,"uris":["http://zotero.org/groups/945096/items/9893MBZH"],"uri":["http://zotero.org/groups/945096/items/9893MBZH"],"itemData":{"id":151,"type":"personal_communication","title":"Letter to Public Water Suppliers concerning new perchlorate regulations","URL":"https://www.mass.gov/lists/perchlorate-background-information-and-standards#perchlorate---final-standards-","author":[{"literal":"MassDEP"}],"issued":{"date-parts":[["2006"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], and California promulgated a drinking water standard of 6 μg/L in 2007 [ADDIN ZOTERO_ITEM CSL_CITATION

{"citationID":"cfr6HNhg","properties":{"formattedCitation":"(California Department of Public Health, 2007)","plainCitation":"(California Department of Public Health, 2007)","noteIndex":0},"citationItems":[{"id":150,"uris":["http://zotero.org/groups/945096/items/RA45NKLQ"],"uri":["http://zotero.org/groups/945096/items/RA45NKLQ"],"itemData":{"id":150,"type":"personal_communication","title":"State Adoption of a Perchlorate Standard","URL":"https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/perchlorate/AdoptionMemotoWaterSystems-10-2007.pdf","author":[{"literal":"California Department of Public Health"}],"issued":{"date-parts":[["2007"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Systems in these states are now required to keep perchlorate levels in drinking water below their state limits, which are lower than the proposed MCL and alternative MCLs. Therefore, the UCMR 1 sampling results from systems in these states do not reflect the current occurrence and exposure conditions. For the purpose of estimating the costs and benefits of the proposed rule, the EPA assumed that no additional monitoring and treatment costs would be incurred by the systems in the States of California and Massachusetts. Systems in California account for some of the perchlorate measurements reported below. The notes in the tables below indicate whether results include or exclude systems in California and Massachusetts.

To update the occurrence data for systems sampled during UCMR 1 from the States of California and Massachusetts, the EPA identified all systems and corresponding entry points which had reported perchlorate detections in UCMR 1. Once the systems and entry points with detections were appropriately identified, the EPA then used a combination of available data from Consumer Confidence Reports (CCRs) and perchlorate compliance monitoring data from California (https://sdwis.waterboards.ca.gov/PDWW/) and Massachusetts (https://www.mass.gov/service-details/public-water-supplier-document-search) to match current compliance monitoring data (where available) to the corresponding water systems and entry points sampled during UCMR 1.

Out of the 540 detections previously described the EPA updated data for 321 detections (320 from California systems and 1 from a Massachusetts system). The convention used by the EPA to accomplish the substitution of data was to match entry points with compliance data for active entry points based on most recently reported compliance monitoring data, if more than one data point was reported for an entry point, the assigned value is an average of the annual monitoring results at the entry point. In cases were the EPA could not find updated entry point data, then the original data from UCMR 1 for such entry point was kept.

Table VI-1. UCMR 1 Data Summary Statistics

Item	Small System Sample	Large System Census	Sum
Total samples	3,295	30,837	34,132
Sample measurements ≥ 4 μg/L	15	525	540
Sample measurements > 18 μg/L	1	16	17
Sample measurements > 56 μg/L	0	2	2
Sample measurements > 90 μg/L	0	1	1
Total entry points	1,454	13,482	14,936
Entry points at which measurements ≥ 4 μg/L	8	328	336
Entry points at which measurements > 18 μg/L	1	16	17
Entry points at which measurements > 56 μg/L	0	2	2
Entry points at which measurements > 90 μg/L	0	1	1
Total systems	797	3,068	3,865
Systems at which measurements ≥ 4 μg/L	8	141	149
Systems at which measurements > 18 μg/L	1	14	15
Systems at which measurements > 56 μg/L	0	2	2
Systems at which measurements > 90 μg/L	0	1	1

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"UAoGFPZv","properties":{"formattedCitation":"(USEPA, 2018)","plainCitation":"(USEPA, 2018)","noteIndex":0},"citationItems":[{"id":969,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":969,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The total row counts and counts of measurements ≥ 4 μg/L identify all instances where perchlorate was detected at or above the minimum reporting level, including water systems in California and Massachusetts, which account for 537 systems in total and 51 systems at which measurements ≥4 μg/L. The instances where perchlorate measurements equal or exceed either 18 μg/L, 56μg/L, or 90 μg/L exclude results from California and Massachusetts because water systems in these States must meet limits below 18 μg/L. The small system counts reflect sample results that have not been extrapolated to small systems nationwide.

Table VI-2 shows the service populations that correspond with the occurrence summary in Table VI-1. The entry point population estimates reflect the assumption that system population is uniformly distributed across entry points; e.g., the entry point population for a system with two entry points is one-half the total system population.

Table VI-2. UCMR1 Data Service Population Summary Statistics

Item	Small System Sample	Large System Census	Sum
Total entry point population	2,760,570	222,853,101	225,613,671
Population served by entry points at which measurements ≥ 4 μg/L	9,484	4,281,937	4,291,420
Population served by entry points at which measurements > 18 μg/L	2,155	618,406	620,560
Population served by entry points at which measurements > 56 μg/L	0	32,432	32,432
Population served by entry points at which measurements > 90 μg/L	0	25,972	25,972
Total system population	2,760,570	222,853,101	225,613,671
Population served by systems at which measurements ≥ 4 μg/L	13,483	16,159,082	16,172,565
Population served by systems at which measurements >18 μg/L	4,309	696,871	701,180
Population served by systems at which measurements > 56 μg/L	0	64,733	64,733
Population served by systems at which measurements > 90 μg/L	0	25,972	25,972

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ChxDKgDr","properties":{"formattedCitation":"(USEPA, 2018)","plainCitation":"(USEPA, 2018)","noteIndex":0},"citationItems":[{"id":969,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":969,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The populations for entry points/systems with measurements ≥ 4 μg/L identify all instances where perchlorate was detected at or above the minimum reporting level, including water systems in California and Massachusetts, which account for 39.6 million of the 225.6 million total population in UCMR 1, and 1.9 million of the 4.3 million population served by entry points at which measurements ≥4 μg/L. The instances where perchlorate measurements equal or exceed either 18 μg/L, 56μg/L, or 90 μg/L exclude results from California and Massachusetts because water systems in these States must meet limits below 18 μg/L. The small system counts reflect sample results that have not been extrapolated to small systems nationwide.

As shown in the tables, 149 systems serving 16.2 million people had measured levels of perchlorate greater than the minimum reporting level. However, many of these systems have several entry points with no measured levels of perchlorate greater than the minimum reporting level; at the entry point level, the exposed population is approximately 4.3 million people served by 336 entry points. Because the uniform population distribution assumption may over or underestimate the service population of any particular entry point, the entry point estimates are uncertain. The system population estimates serve as upper bounds on exposure.

The EPA used entry point maximum measurements to estimate potential baseline occurrence and exposure at levels that exceed the proposed MCL and alternative MCLs. The maximum measurements indicate perchlorate levels that occurred in at least one quarterly sample among surface water systems and at least one semi-annual sample among ground water systems.

Table VI-3 through Table VI-5 show the occurrence and exposure estimates based on the 56 μg/L, 18 μg/L MCL, and 90 μg/L values, respectively. Each table provides estimates of the entry points at which the maximum perchlorate concentrations exceed the MCL value. The tables also report the system-level information for these entry points.

Table VI-3: Estimated Perchlorate Occurrence and Exposure: Entry Point Max Exceeds 56 μg/L

Affected Entity	Small Systems	Large Systems	Total Systems
Entry points	0	2	2
Population served	0	32,432	32,432
Water systems	0	2	2
Population served	0	64,733	64,733

Source: [ADDIN ZOTERO_ITEM CSL_CITATION
{"citationID":"adhRbcXq","properties":{"formattedCitation":"(USEPA, 2018c)","plainCitation":"(USEPA, 2018c)","noteIndex":0},"citationItems":[{"id":155,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":155,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Table VI-4: Estimated Perchlorate Occurrence and Exposure: Entry Point Max Exceeds 18 μg/L

Affected Entity	Small Systems[1]	Large Systems	Total Systems
Entry points	1	16	17
Population served	2,155	618,406	620,560
Water systems	1	14	15
Population served	4,309	696,871	701,180

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"z4saRTHP","properties":{"formattedCitation":"(USEPA, 2018c)","plainCitation":"(USEPA, 2018c)","noteIndex":0},"citationItems":[{"id":155,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":155,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

1. The values shown in the table are estimates based on the UCMR 1 data. The EPA also applied the statistical sampling weights to the results to extrapolate results to national results. The entry point at which a measurement exceeds 18 μg/L is one of 20 in its sample stratum; no other sample in the stratum had a measurement of perchlorate greater than the minimum reporting level. The entry point population of 2,155 represents 5.31% of the total population served by the six UCMR 1 systems in the stratum (40,574). Currently, the stratum population of 774,780 accounts for 1.32% of the 58.7 million national population served by small systems. Thus, the UCMR 1 results indicate that 0.07% (5.31% x 1.32%) of small system customers (approximately 41,100) may be exposed to perchlorate greater than 18 μg/L.

Table VI-5: Estimated Perchlorate Occurrence and Exposure: Entry Point Max Exceeds 90 µg/L

Affected Entity	Small Systems[1]	Large Systems	Total Systems
Entry points	0	1	1
Population served	0	25,972	25,972
Water systems	0	1	1
Population served	0	25,972	25,972

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"z4saRTHP","properties":{"formattedCitation":"(USEPA, 2018c)","plainCitation":"(USEPA, 2018c)","noteIndex":0},"citationItems":[{"id":155,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":155,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

In summary, the perchlorate occurrence information suggests that at an MCL of 56 µg/L, two systems (0.004% of all water systems in the U.S.) would exceed the regulatory threshold. One of these two systems would exceed the alternative MCL of 90 µg/L. In addition, at an MCL of 18 µg/L, there would be 15 systems (0.03% of all water systems in the U.S.) that would exceed the regulatory threshold.

VII. Analytical Methods

The SDWA directs the EPA to set a contaminant's MCL as close to its MCLG as is ''feasible'', the definition of which includes an evaluation of the feasibility of performing chemical analysis of the contaminant at standard drinking water laboratories. Specifically, the

SDWA directs the EPA to determine that it is economically and technologically feasible to ascertain the level of the contaminant being regulated in water in public water systems (Section 1401(1)(C)(i)). NPDWRs are also to contain ''criteria and procedures to assure a supply of drinking water which dependably complies with such [MCLs]; including accepted methods for quality control and testing procedures to insure compliance with such levels.'' (Section 1401(1)(D)).

To comply with these requirements, the EPA considers method performance under relevant laboratory conditions, their likely prevalence in certified drinking water laboratories, and the associated analytical costs. The EPA has developed five analytical methods for the identification and quantification of perchlorate in drinking water that meet these criteria. The proposed EPA methods for perchlorate are: 314.0, 314.1, 314.2, 331.0, and 332.0. A detailed description of these methods is presented in the Perchlorate Occurrence and Monitoring Report (USEPA, 2019b).

The EPA Methods 314.0, 314.1, 314.2, 331.0, and 332.0 underwent the EPA's analytical method development and validation processes. The validation process includes a protocol for modifications to any existing EPA-approved analytical methods and a protocol for new determinative techniques. Both validation protocols are rigorous and consider many technical aspects of analytical method performance, including: detection limits; instrument calibration; precision and analyte recovery; analyte retention times; evaluation of blanks; development of Quality Control acceptance criteria; analysis of field samples; and other technical aspects of sample analysis and data reporting. All of the proposed EPA analytical methods provide performance data to demonstrate their capability to reliably and consistently measure perchlorate in drinking water at the proposed and alternate MCLs.

VIII. Monitoring and Compliance Requirements

A. What are the Proposed Monitoring Requirements?

The EPA is proposing to require CWS and NTNCWSs to monitor for perchlorate in accordance with the standardized monitoring framework set out in 40 CFR 141 Subpart C (Standardized Monitoring Framework). Public water systems must sample entry points to the distribution system consistent with requirements in 40 CFR 141.23(a).

Under the Standardized Monitoring Framework, the monitoring frequency for a public water system is dependent on previous monitoring results and whether a monitoring waiver has been granted. The EPA is proposing that consistent with the standardized monitoring framework water systems would be initially required to monitor quarterly for perchlorate. The EPA is also proposing that based upon the monitoring results States would be able to reduce the monitoring frequency to annually, once every three years or once every nine years if the State concludes that the system is reliably and consistently below the MCL. If a water system exceeds the perchlorate MCL, the system is in violation and triggered into quarterly monitoring for that sampling point in the next quarter after the violation occurred (40 CFR 141.23(c)(7)). The state may allow the system to return to the reduced monitoring frequency when the state determines that the system is reliably and consistently below the MCL. However, the state cannot make a determination that the system is reliably and consistently below the MCL until a minimum of 2 consecutive ground water or 4 consecutive surface water samples below the MCL have been collected (40 CFR 141.23(c)(8)). All systems must comply with the sampling requirements, unless a waiver has been granted in writing by the state (40 CFR 141.23(c)(6)).

B. Can States Grant Monitoring Waivers?

Under this proposal, water systems may apply to the state, and states may grant, a 9-year monitoring waiver for perchlorate if the conditions described in 40 CFR 141.23(c)(3)-(6) are met. A state may grant a waiver for surface water systems after three rounds of annual monitoring with results less than the MCL and for groundwater systems after conducting three rounds of monitoring with results less than the MCL. One sample must be collected during the nine-year compliance cycle that the waiver is effective, and the waiver must be renewed every nine years.

C. How are System MCL Violations Determined?

Under this proposal, violations of the perchlorate MCL would be determined in a manner consistent with 40 CFR 141.23(i)(3). Compliance with the perchlorate MCL would be determined based on one sample if the level is below the MCL. If the level of perchlorate exceeds the MCL at any entry point in the initial sample, a confirmation sample is required within two weeks of the system's receipt of notification of the analytical result of the first sample, in accordance with 141.23(f)(1). Compliance shall be determined based on the average of the initial and confirmation samples.

D. When Must Systems Complete Initial Monitoring?

Pursuant to Section 1412(b)(10), this rule would be effective three years after promulgation. To satisfy initial monitoring requirements, CWS serving populations greater than 10,000 persons must collect 4 quarterly samples for perchlorate during the second compliance period of the fourth compliance cycle (January 1, 2023– December 31, 2025) of the Standardized Monitoring Framework. NTNCWS and CWSs serving 10,000 persons or less must collect 4 quarterly samples during the third compliance period of the fourth compliance cycle (January 1, 2026 – December 31, 2028) of the Standardized Monitoring Framework.

E. Can Systems use Grandfathered Data to Satisfy the Initial Monitoring Requirements?

As proposed today, systems would be allowed to use grandfathered perchlorate data collected after January 1, 2020, to satisfy the initial monitoring requirements. To satisfy initial perchlorate monitoring requirements, a system with appropriate historical monitoring data for each entry point to the distribution system could use the monitoring data from the compliance monitoring period between January 1, 2020, and December 31, 2022, for CWSs serving greater than 10,000 persons and between January 1, 2023, and December 31, 2025, for NTNCWs and for CWSs serving 10,000 or fewer persons.

IX. Safe Drinking Water Act Right to Know Requirements

A. What are the Consumer Confidence Report Requirements?

A community water system must prepare and deliver to its customers an annual Consumer Confidence Report (CCR) in accordance with requirements in 40 CFR 141 Subpart O.

A CCR provides customers with information about their local drinking water quality as well as information regarding the water system compliance with drinking water regulations. Under this proposal CWSs would be required to report perchlorate information in their CCR.

B. What are the Public Notification Requirements?

All public water systems must give the public notice for all violations of NPDWRs and for other situations. Under this proposal, violations of the perchlorate MCL would be designated as Tier 1 and as such, public water systems would be required to comply with 40 CFR 141.202. As described in Section III of this proposal, fetuses of first trimester pregnant women with low iodine are the most sensitive subpopulation, therefore, per 40 CFR 141.202(b)(1), notification of an MCL violation should be provided as soon as practicable but no later than 24 hours after the system learns of the violation under this proposal.

X. Treatment Technologies

Systems that exceed the perchlorate MCL will need to adopt new treatment or another strategy to reduce perchlorate to a level that meets the MCL. When the EPA establishes an MCL for a drinking water contaminant, Section 1412(b)(4)(E) of the SDWA requires that the Agency "list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting [the MCL]," which are referred to as best available technologies (BAT). These BATs are used by states to establish conditions for source water variances under Section 1415(a). Furthermore, Section 1412(b)(4)(E)(ii) requires that the Agency identify small system compliance technologies (SSCT), which are affordable treatment technologies, or other means that can achieve compliance with the MCL (or treatment technique, where applicable). The lack of an affordable SSCT for a contaminant triggers certain additional procedures which can result in states issuing small system variances under Section 1412(e) of the SDWA.

The Agency solicits public comment on the choice of available treatment technologies discussed in this section.

A. What are the Best Available Technologies?

The Agency identifies the best available technologies (BAT) as those meeting the following criteria: (1) the capability of a high removal efficiency; (2) a history of full-scale operation; (3) general geographic applicability; (4) reasonable cost based on large and metropolitan water systems; (5) reasonable service life; (6) compatibility with other water treatment processes; and (7) the ability to bring all of the water in a system into compliance. The Agency is proposing the following technologies as BAT for removal of perchlorate from drinking water based its review of the treatment and cost literature (USEPA, 2018a):

- ion exchange;
- biological treatment; and
- centralized reverse osmosis.

There are also non-treatment options that might be used for compliance in lieu of installing and operating treatment technologies. These include blending existing water sources, replacing a perchlorate-contaminated source of drinking water with a new source (e.g., a new well), and purchasing compliant water from another system. Below are brief descriptions of each proposed BAT.

Ion Exchange.

Ion exchange is a physical and chemical separation process that can achieve high perchlorate removal rates. Feed water passes through a vessel containing a bed of resin made of synthetic beads or gel. As feed water moves through the resin, an ionic contaminant such as perchlorate exchanges for an ion (typically chloride) on the resin. Demonstrated removal efficiencies for perchlorate are typically in the high 90 percent range and can achieve concentrations less than 4 μg/L in treated water [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"s9dVZckb","properties":{"formattedCitation":"(Drago & Leserman, 2011; Membrane Technology, 2006; Siemens Water Technologies, 2009; The Interstate Technology & Regulatory Council (ITRC) Team, 2008)","plainCitation":"(Drago & Leserman, 2011; Membrane Technology, 2006; Siemens Water Technologies, 2009; The Interstate Technology & Regulatory Council (ITRC) Team, 2008)","noteIndex":0},"citationItems":[{"id":1048,"uris":["http://zotero.org/groups/945096/items/KIPNEQUM"],"uri":["http://zotero.org/groups/945096/items/KIPNEQUM"],"itemData":{"id":1048,"type":"paper-conference","title":"Castaic Lake Water Agency Operating Experience with Lead-Lag Anion Exchange for Perchlorate Removal","container-title":"Proceedings of the American Water Works Association Water Quality Technology Conference","event":"Water Quality Technology

Conference","author":[{"family":"Drago","given":"J.A."},{"family":"Leserman","given":"J.R."}],"issued":{"date-parts":[["2011",11]]}}},{"id":1154,"uris":["http://zotero.org/groups/945096/items/2DBS6UYD"],"uri":["http://zotero.org/groups/945096/items/2DBS6UYD"],"itemData":{"id":1154,"type":"article","title":"News: Ion=Exchange System Removes Perchlorate","publisher":"Membrane Technology","author":[{"literal":"Membrane Technology"}],"issued":{"date-parts":[["2006",4]]}}},{"id":1125,"uris":["http://zotero.org/groups/945096/items/6WYYWFY2"],"uri":["http://zotero.org/groups/945096/items/6WYYWFY2"],"itemData":{"id":1125,"type":"report","title":"Case Study: Municipality in the State of Massachusetts","author":[{"literal":"Siemens Water Technologies"}],"issued":{"date-parts":[["2009"]]}}},{"id":1118,"uris":["http://zotero.org/groups/945096/items/5PV8GPIA"],"uri":["http://zotero.org/groups/945096/items/5PV8GPIA"],"itemData":{"id":1118,"type":"article","title":"Technical/Regulatory Guidance: Remediation Technologies for Perchlorate Contamination in Water and Soil","URL":"http://www.eosremediation.com/download/Perchlorate/ITRC%20PERC-2.pdf","author":[{"literal":"The Interstate Technology & Regulatory Council (ITRC) Team"}],"issued":{"date-parts":[["2008",3]]},"accessed":{"date-parts":[["2018",10,13]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The operation continues until enough of the resin's available ion exchange sites have ions from the feed water and the resin no longer effectively removes the target contaminant, i.e., the contaminant “breaks through” the treatment process. At this point, the resin must be disposed and replaced or regenerated. The length of time until resin must be replaced or regenerated is known as bed life and is a critical factor in the cost effectiveness of ion exchange as a treatment technology. One measurement of bed life is the volume of water that can be treated before breakthrough – called bed volumes – the number of times the resin bed can be filled before breakthrough. Several factors affect bed life, including the presence of competing ions such as nitrate and the type of resin used. Resin types tested for perchlorate removal include strong-base polyacrylic, strong-base polystyrenic (including nitrate-selective), weak-base polyacrylic, weak-base polystyrenic, and perchlorate-selective. Based on studies of the effect of competing ions on performance, perchlorate-selective resins can achieve bed lives ranging from 105,000 to 170,000 bed volumes [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"cxQjBTo8","properties":{"formattedCitation":"(Blute, Seidel, McGuire, Qin, & Byerrum, 2006; Russell, Qin, Blute, McGuire, & Williams, 2008; Wu & Blute, 2010)","plainCitation":"(Blute, Seidel, McGuire, Qin, & Byerrum, 2006; Russell, Qin, Blute, McGuire, & Williams, 2008; Wu & Blute, 2010)","noteIndex":0},"citationItems":[{"id":1076,"uris":["http://zotero.org/groups/945096/items/8Z7K9ZUJ"],"uri":["http://zotero.org/groups/945096/items/8Z7K9ZUJ"],"itemData":{"id":1076,"type":"speech","title":"Bench and Pilot Testing of High Capacity, Single-Pass Ion Exchange Resins for Perchlorate Removal","publisher-place":"San Antonio, TX","event":"2006 AWWA Annual Conference & Exposition","event-place":"San Antonio, TX","author":[{"family":"Blute","given":"N.K."},{"family":"Seidel","given":"C.J."},{"family":"McGuire","given":"M.J."},{"family":"Qin","given":"D."},{"family":"Byerrum","given":"J."}],"issued":{"date-parts":[["2006",6]]}}},{"id":1132,"uris":["http://zotero.org/groups/945096/items/NLAFHBV2"],"uri":["http://zotero.org/groups/945096/items/NLAFHBV2"],"itemData":{"id":1132,"type":"speech","title":"Pilot Testing of Single Pass Perchlorate-Selective Ion Exchange Resins at Three Utilities in the Main San Gabriel Basin","publisher-place":"Cincinnati, OH","event":"AWWA Water Quality Technology Conference & Exposition","event-place":"Cincinnati, OH","author":[{"family":"Russell","given":"C.G."},{"family":"Qin","given":"G."},{"family":"Blute","given":"N.K."},{"family":"McGuire","given":"M.J."},{"family":"Williams","given":"C."}],"issued":{"date-parts":[["2008",11]]}}},{"id":1094,"uris":["http://zotero.org/groups/945096/items/2QPEXW23"],"uri":["http://zotero.org/groups/945096/items/2QPEXW23"],"itemData":{"id":1094,"type":"speech","title":"Perchlorate Removal Using Single-Pass Ion Exchange Resin - Pilot Testing Purolite A532E at the San Gabriel B6 Plant","publisher-place":"Hollywood, CA","event":"2010 California-Nevada AWWA Spring Conference","event-place":"Hollywood, CA","author":[{"family":"Wu","given":"X."},{"family":"Blute","given":"N.K."}],"issued":{"date-parts":[["2010",3,31]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Perchlorate-selective resin cannot be easily regenerated for reuse; the exhausted resin must be disposed (i.e., operated on a 'throw-away' basis). This mode of operation, however, avoids the production of liquid residuals in the form of spent regenerant. Therefore, in combination with the long bed life, single-use perchlorate-selective ion exchange can be a cost-effective treatment option in spite of the need to dispose of the perchlorate-contaminated resin. Build-up of arsenic or uranium on the resin may affect waste disposal options, although studies of perchlorate-selective resins show that arsenic concentrations remain below regulatory limits for hazardous waste disposal and uranium concentrations generally remain below those that require special handling as radioactive waste [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"I0SaZZiL","properties":{"formattedCitation":"(Blute et al., 2006; Russell et al., 2008; Wu & Blute, 2010)","plainCitation":"(Blute et al., 2006; Russell et al., 2008; Wu & Blute, 2010)","noteIndex":0},"citationItems":[{"id":1076,"uris":["http://zotero.org/groups/945096/items/8Z7K9ZUJ"],"uri":["http://zotero.org/groups/945096/items/8Z7K9ZUJ"],"itemData":{"id":1076,"type":"speech","title":"Bench and Pilot Testing of High Capacity, Single-Pass Ion Exchange Resins for Perchlorate Removal","publisher-place":"San Antonio, TX","event":"2006 AWWA Annual Conference & Exposition","event-place":"San Antonio, TX","author":[{"family":"Blute","given":"N.K."},{"family":"Seidel","given":"C.J."},{"family":"McGuire","given":"M.J."},{"family":"Qin","given":"D."},{"family":"Byerrum","given":"J."}],"issued":{"date-parts":[["2006",6]]}}},{"id":1132,"uris":["http://zotero.org/groups/945096/items/NLAFHBV2"], "uri":["http://zotero.org/groups/945096/items/NLAFHBV2"],"itemData":{"id":1132,"type":"speech","title":"Pilot Testing of Single Pass Perchlorate-Selective Ion Exchange Resins at Three Utilities in the Main San Gabriel Basin","publisher-place":"Cincinnati, OH","event":"AWWA Water Quality Technology Conference & Exposition","event-place":"Cincinnati, OH","author":[{"family":"Russell","given":"C.G."},{"family":"Qin","given":"G."},{"family":"Blute","given":"N.K."},{"family":"McGuire","given":"M.J."},{"family":"Williams","given":"C."}],"issued":{"date-parts":[["2008",11]]}}},{"id":1094,"uris":["http://zotero.org/groups/945096/items/2QPEXW23"],"uri":["http://zotero.org/groups/945096/items/2QPEXW23"],"itemData":{"id":1094,"type":"speech","title":"Perchlorate Removal Using Single-Pass Ion Exchange Resin - Pilot Testing Purolite A532E at the San Gabriel B6 Plant","publisher-place":"Hollywood, CA","event":"2010 California-Nevada AWWA Spring Conference","event-place":"Hollywood, CA","author":[{"family":"Wu","given":"X."},{"family":"Blute","given":"N.K."}],"issued":{"date-parts":[["2010",3,31]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Ion exchange can increase the corrosivity of treated water [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"dcLyBjzj","properties":{"formattedCitation":"(Berlien, 2003; Betts, 1998; USEPA, 2005b)","plainCitation":"(Berlien, 2003; Betts, 1998; USEPA, 2005b)","noteIndex":0},"citationItems":[{"id":1079,"uris":["http://zotero.org/groups/945096/items/8PB22K95"],"uri":["http://zotero.org/groups/945096/items/8PB22K95"],"itemData":{"id":10

79,"type":"report","title":"La Puente Valley County Water District's Experience with ISEP","collection-title":"Presentation of Carollo Engineers, Inc. and Association of California Water Agencies","author":[{"family":"Berlien","given":"M.J."}],"issued":{"date-parts":[["2003",4]]}}},{"id":1078,"uris":["http://zotero.org/groups/945096/items/BNWD5VQP"],"uri":["http://zotero.org/groups/945096/items/BNWD5VQP"],"itemData":{"id":1078,"type":"article-journal","title":"Rotation ion-exchange system removes perchlorate","page":"454A-455A","volume":"32","journalAbbreviation":"Environ. Sci. Technol.","author":[{"family":"Betts","given":"K.S."}],"issued":{"date-parts":[["1998"]]}}},{"id":1208,"uris":["http://zotero.org/groups/945096/items/EWAQ4GEK"],"uri":["http://zotero.org/groups/945096/items/EWAQ4GEK"],"itemData":{"id":1208,"type":"article","title":"Perchlorate Treatment Technology Update: Federal Facilities Forum Issue Paper","publisher":"Office of Solid Waste and Emergency Response. EPA 542-R-05-015","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2005",5]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] because of the addition of chloride ions and/or removal of carbonates and bicarbonates. Such instances can be addressed by adding or adjusting corrosion control.

Biological Treatment.

Biological treatment uses bacteria to reduce perchlorate to chlorate, chlorite, chloride, and oxygen. Biological treatment can destroy the perchlorate ion, eliminating the need for management of perchlorate-bearing waste streams. Removal effectiveness exceeds 90 percent for bench-scale tests and full-scale treatment plant studies [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"CnYkqct9","properties":{"formattedCitation":"(Kotlarz, Upadhyaya, Togna, & Raskin, 2016; Upadhyaya, Kotlarz, Togna, & Raskin, 2015; U.S. Department of Defense (U.S. DoD), 2008, 2009; T. D. Webster & Crowley, 2010, 2016; T. D. Webster & Litchfield, 2017)","plainCitation":"(Kotlarz, Upadhyaya, Togna, & Raskin, 2016; Upadhyaya, Kotlarz, Togna, & Raskin, 2015; U.S. Department of Defense (U.S. DoD), 2008, 2009; T. D. Webster & Crowley, 2010, 2016; T. D. Webster & Litchfield, 2017)","noteIndex":0},"citationItems":[{"id":1019,"uris":["http://zotero.org/groups/945096/items/E5WRR4HD"],"uri":["http://zotero.org/groups/945096/items/E5WRR4HD"],"itemData":{"id":1019,"type":"article-journal","title":"Evaluation of electron donors for biological perchlorate removal highlights the importance of diverse perchlorate-reducing populations","container-title":"Environmental Science: Water Research & Technology","page":"1049-1063","volume":"2","author":[{"family":"Kotlarz","given":"N."},{"family":"Upadhyaya","given":"G."},{"family":"Togna","given":"P."},{"family":"Raskin","given":"L."}],"issued":{"date-parts":[["2016"]]}}},{"id":1106,"uris":["http://zotero.org/groups/945096/items/KLWCLIE4"],"uri":["http://zotero.org/groups/945096/items/KLWCLIE4"],"itemData":{"id":1106,"type":"article-journal","title":"Carbohydrate-Based Electron Donor for Biological Nitrate and Perchlorate Removal From Drinking Water","container-title":"Journal - American Water Works Association","page":"E674-E684","volume":"107","issue":"12","source":"Wiley Online

Library","abstract":"This study evaluated the feasibility of replacing acetic acid with a commercial carbohydrate-based electron donor (CBED) for removal of nitrate and perchlorate (ClO4–) from drinking water. Bench-scale biologically active carbon fixed-bed and fluidized-bed reactors (FXBR and FLBR, respectively), with an initial empty bed contact time (EBCT) of 42.8 min, were fed simulated groundwater containing 15 mg/L nitrate as nitrogen and 200 μg/L ClO4–. EBCT in the FLBR after final expansion was 80.5 min. During the first 100 days using acetic acid at 125 mg/L chemical oxygen demand (COD), complete nitrate removal was achieved in both systems, whereas perchlorate in the FXBR and FLBR effluents remained below 3 and 6 μg/L ClO4–, respectively. For comparable removals, influent COD requirement was higher with the CBED. Biomass yields with acetic acid and the CBED were 0.54–0.58 and 0.59–0.74 mg CODbiomass/mg CODsubstrate, respectively. The higher yield with the CBED resulted in more frequent maintenance requirements.","DOI":"10.5942/jawwa.2015.107.0143","ISSN":"1551-8833","language":"en","author":[{"family":"Upadhyaya","given":"Giridhar"},{"family":"Kotlarz","given":"Nadine"},{"family":"Togna","given":"Paul"},{"family":"Raskin","given":"Lutgarde"}],"issued":{"date-parts":[["2015",12,1]]}}},{"id":1110,"uris":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"uri":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"itemData":{"id":1110,"type":"report","title":"Perchlorate Removal, Destruction, and Field Monitoring Demonstration (Drinking Water - Pilot Scale)","collection-title":"ESTCP Cost and Performance Report (ER-0312)","author":[{"literal":"U.S. Department of Defense (U.S. DoD)"}],"issued":{"date-parts":[["2008"]]}}},{"id":1116,"uris":["http://zotero.org/groups/945096/items/9FHLVTXY"],"uri":["http://zotero.org/groups/945096/items/9FHLVTXY"],"itemData":{"id":1116,"type":"report","title":"Demonstration of a Full-Scale Fluidized Bed Bioreactor for the Treatment of Perchlorate at Low Concentrations in Groundwater","genre":"Environmental Security Technology Certification Program (ESTCP) Final Report (ER-0543)","author":[{"family":"U.S. Department of Defense (U.S. DoD)","given":""}],"issued":{"date-parts":[["2009"]]}}},{"id":1093,"uris":["http://zotero.org/groups/945096/items/BI7SF8HW"],"uri":["http://zotero.org/groups/945096/items/BI7SF8HW"],"itemData":{"id":1093,"type":"speech","title":"Full-Scale Implementation of a Biological Fluidized Bed Drinking Water Treatment Plant for Nitrate and Perchlorate Treatment","publisher-place":"Ontario, CA","event":"2010 Water Education Foundation Water Quality and Regulatory Conference","event-place":"Ontario, CA","author":[{"family":"Webster","given":"T.D."},{"family":"Crowley","given":"T.J."}],"issued":{"date-parts":[["2010",11,3]]}}},{"id":989,"uris":["http://zotero.org/groups/945096/items/BI5LYMZP"],"uri":["http://zotero.org/groups/945096/items/BI5LYMZP"],"itemData":{"id":989,"type":"speech","title":"Biological treatment of perchlorate in groundwater.","event":"AWWA Annual Conference and Exposition","author":[{"family":"Webster","given":"T.D."},{"family":"Crowley","given":"T.J."}],"issued":{"date-parts":[["2016",6,21]]}}},{"id":990,"uris":["http://zotero.org/groups/945096/items/64HZKA2M"

],"uri":["http://zotero.org/groups/945096/items/64HZKA2M"],"itemData":{"id":990,"type":"article-journal","title":"Full-scale biological treatment of nitrate and perchlorate for potable water production","container-title":"Journal AWWA","page":"30-40","volume":"109","issue":"5","author":[{"family":"Webster","given":"T.D."},{"family":"Litchfield","given":"M.H."}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Although biological treatment is a relatively new technology for treatment of drinking water in the United States, the State of California has identified biological treatment (along with ion exchange) as one of two best available technologies for achieving compliance with its standard for perchlorate in drinking water (California Code of Regulations, Title 22, Chapter 15, Section 64447.2). The California BAT specifies a fluidized bed, although studies suggest that a fixed bed is also effective. The first full-scale fluidized bed facility using biological treatment of perchlorate to supply municipal drinking water began operation in 2016 [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"nKwIqjde","properties":{"formattedCitation":"(T. D. Webster & Crowley, 2016; T. D. Webster & Litchfield, 2017)","plainCitation":"(T. D. Webster & Crowley, 2016; T. D. Webster & Litchfield, 2017)","noteIndex":0},"citationItems":[{"id":989,"uris":["http://zotero.org/groups/945096/items/BI5LYMZP"],"uri":["http://zotero.org/groups/945096/items/BI5LYMZP"],"itemData":{"id":989,"type":"speech","title":"Biological treatment of perchlorate in groundwater.","event":"AWWA

Annual Conference and Exposition","author":[{"family":"Webster","given":"T.D."},{"family":"Crowley","given":"T.J."}],"issued":{"date-parts":[["2016",6,21]]}}},{"id":990,"uris":["http://zotero.org/groups/945096/items/64HZKA2M"],"uri":["http://zotero.org/groups/945096/items/64HZKA2M"],"itemData":{"id":990,"type":"article-journal","title":"Full-scale biological treatment of nitrate and perchlorate for potable water production","container-title":"Journal AWWA","page":"30-40","volume":"109","issue":"5","author":[{"family":"Webster","given":"T.D."},{"family":"Litchfield","given":"M.H."}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Raw water quality will affect process design, in particular, temperature affects the rate of biomass growth; at temperatures below 10 degrees Celsius, growth is inhibited and bioremediation becomes infeasible [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ISPg08cl","properties":{"formattedCitation":"(Dugan, 2010b, 2010a; Dugan et al., 2009)","plainCitation":"(Dugan, 2010b, 2010a; Dugan et al., 2009)","noteIndex":0},"citationItems":[{"id":1047,"uris":["http://zotero.org/groups/945096/items/X3WWHCXS"],"uri":["http://zotero.org/groups/945096/items/X3WWHCXS"],"itemData":{"id":1047,"type":"speech","title":"The Impact of Temperature on Biological Perchlorate Removal and Downstream Effluent Polishing","publisher-place":"U.S. Environmental Protection Agency, Office of Research and Development, National Risk Management Research Laboratory","event-place":"U.S. Environmental Protection Agency, Office of Research and Development, National Risk Management Research Laboratory","author":[{"family":"Dugan","given":"N.R."}],"issued":{"date-parts":[["2010",12,8]]}}},{"id":1046,"uris":["http://zotero.org/groups/945096/items/IIXUW45F"],"uri":["http://zotero.org/groups/945096/items/IIXUW45F"],"itemData":{"id":1046,"type":"article","title":"Supporting data for presentation: The Impact of Temperature on Biological Perchlorate Removal and Downstream Effluent Polishing","publisher":"U.S. Environmental Protection Agency, Office of Research and Development, National Risk Management Research Laboratory","author":[{"family":"Dugan","given":"N.R."}],"issued":{"date-parts":[["2010",12,8]]}}},{"id":1045,"uris":["http://zotero.org/groups/945096/items/FLVLSXCS"],"uri":["http://zotero.org/groups/945096/items/FLVLSXCS"],"itemData":{"id":1045,"type":"speech","title":"The Impact of Temperature on Anaerobic Biological Perchlorate Treatment","publisher-place":"Seattle, WA","event":"2009 AWWA Water Quality Technology Conference & Exposition","event-place":"Seattle, WA","author":[{"family":"Dugan","given":"N.R."},{"family":"Williams","given":"D.J."},{"family":"Meyer","given":"M."},{"family":"Schneider","given":"R.R."},{"family":"Speth","given":"T.F."},{"family":"Metz","given":"D.H."}],"issued":{"date-parts":[["2009"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. This factor limits the feasibility of biological treatment in areas that experience low water temperatures during winter. In addition, bacteria in bioreactors require nutrients to grow and effectively reduce perchlorate. Therefore, some source waters may require supplemental addition of nutrients such as nitrogen or phosphorus [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"NDoHjLOr","properties":{"formattedCitation":"(Harding Engineering and Environmental Services (ESE), 2001; U.S. Department of Defense (U.S. DoD), 2008a, 2009)","plainCitation":"(Harding Engineering and Environmental Services (ESE), 2001; U.S. Department of Defense (U.S. DoD), 2008a, 2009)","noteIndex":0},"citationItems":[{"id":1139,"uris":["http://zotero.org/groups/945096/items/ZPGXUZPL"],"uri":["http://zotero.org/groups/945096/items/ZPGXUZPL"],"itemData":{"id":1139,"type":"report","title":"Final: Phase 2 Treatibility Study Report, Aerojet GET E/F Treatment Facility, Sacramento, California","collection-title":"Prepared for U.S. Environmental Protection Agency Region IX and Baldwin Park Operable Unit Cooperating Respondents, San Gabriel Basin,California","author":[{"family":"Harding Engineering and Environmental Services (ESE)","given":""}],"issued":{"date-parts":[["2001"]]}}},{"id":1074,"uris":["http://zotero.org/groups/945096/items/2ZCNIFHT"],"uri":["http://zotero.org/groups/945096/items/2ZCNIFHT"],"itemData":{"id":1074,"type":"report","title":"Direct Fixed-bed Biological Perchlorate Destruction Demonstration","genre":"ESTCP Final Report (ER-0544)","author":[{"literal":"U.S. Department of Defense (U.S. DoD)"}],"issued":{"date-parts":[["2008",9,25]]}}},{"id":1081,"uris":["http://zotero.org/groups/945096/items/9FHLVTX

Y"],"uri":["http://zotero.org/groups/945096/items/9FHLVTXY"],"itemData":{"id":1081,"type":"report","title":"Demonstration of a Full-Scale Fluidized Bed Bioreactor for the Treatment of Perchlorate at Low Concentrations in Groundwater","genre":"Environmental Security Technology Certification Program (ESTCP) Final Report (ER-0543)","author":[{"family":"U.S. Department of Defense (U.S. DoD)","given":""}],"issued":{"date-parts":[["2009"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Although the process does not produce perchlorate-contaminated wastes, periodic removal of excess biomass, e.g., through backwash, will be required. The backwash water is non-toxic and can be discharged to a sanitary sewer [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"f4qlOob5","properties":{"formattedCitation":"(U.S. Department of Defense (U.S. DoD), 2008, 2009)","plainCitation":"(U.S. Department of Defense (U.S. DoD), 2008, 2009)","noteIndex":0},"citationItems":[{"id":1110,"uris":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"uri":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"itemData":{"id":1110,"type":"report","title":"Perchlorate Removal, Destruction, and Field Monitoring Demonstration (Drinking Water - Pilot Scale)","collection-title":"ESTCP Cost and Performance Report (ER-0312)","author":[{"literal":"U.S. Department of Defense (U.S. DoD)"}],"issued":{"date-parts":[["2008"]]}}},{"id":1116,"uris":["http://zotero.org/groups/945096/items/9FHLVTXY"],"uri":["http://zotero.org/groups/945096/items/9FHLVTXY"],"itemData":{"id":1116,"type":"report

","title":"Demonstration of a Full-Scale Fluidized Bed Bioreactor for the Treatment of Perchlorate at Low Concentrations in Groundwater","genre":"Environmental Security Technology Certification Program (ESTCP) Final Report (ER-0543)","author":[{"family":"U.S. Department of Defense (U.S. DoD)","given":""}],"issued":{"date-parts":[["2009"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] or recycled following clarification. Typically, post-treatment of treated water also will be required because biological treatment increases soluble microbial organic products, depletes oxygen, and can add turbidity and sulfides [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ySKwU3Em","properties":{"formattedCitation":"(Dordelmann, 2009; Harding Engineering and Environmental Services (ESE), 2001; U.S. Department of Defense (U.S. DoD), 2008; T. D. Webster & Crowley, 2016; T. D. Webster & Litchfield, 2017)","plainCitation":"(Dordelmann, 2009; Harding Engineering and Environmental Services (ESE), 2001; U.S. Department of Defense (U.S. DoD), 2008; T. D. Webster & Crowley, 2016; T. D. Webster & Litchfield, 2017)","noteIndex":0},"citationItems":[{"id":1051,"uris":["http://zotero.org/groups/945096/items/Z7PC3BME"],"uri":["http://zotero.org/groups/945096/items/Z7PC3BME"],"itemData":{"id":1051,"type":"speech","title":"Full-Scale Biological Denitrification Plants in Germany, Austria and Poland","publisher-place":"Seattle, WA","event":"2009 AWWA Water Quality Technology Conference & Exposition","event-place":"Seattle, WA","author":[{"family":"Dordelmann","given":"O."}],"issued":{"date-parts":[["2009",11]]}}},{"id":1026,"uris":["http://zotero.org/groups/945096/items/ZPGXUZPL"],"uri":["http://zotero.org/groups/945096/items/ZPGXUZPL"],"itemData":{"id":1026,"type":"report","title":"Final: Phase 2 Treatibility Study Report, Aerojet GET E/F Treatment Facility, Sacramento, California","collection-title":"Prepared for U.S. Environmental Protection Agency Region IX and Baldwin Park Operable Unit Cooperating Respondents, San Gabriel Basin,California","author":[{"family":"Harding Engineering and Environmental Services (ESE)","given":""}],"issued":{"date-parts":[["2001"]]}}},{"id":1110,"uris":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"uri":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"itemData":{"id":1110,"type":"report","title":"Perchlorate Removal, Destruction, and Field Monitoring Demonstration (Drinking Water - Pilot Scale)","collection-title":"ESTCP Cost and Performance Report (ER-0312)","author":[{"literal":"U.S. Department of Defense (U.S. DoD)"}],"issued":{"date-parts":[["2008"]]}}},{"id":989,"uris":["http://zotero.org/groups/945096/items/BI5LYMZP"],"uri":["http://zotero.org/groups/945096/items/BI5LYMZP"],"itemData":{"id":989,"type":"speech","title":"Biological treatment of perchlorate in groundwater.","event":"AWWA Annual Conference and Exposition","author":[{"family":"Webster","given":"T.D."},{"family":"Crowley","given":"T.J."}],"issued":{"date-parts":[["2016",6,21]]}}},{"id":990,"uris":["http://zotero.org/groups/945096/items/64HZKA2M"

],"uri":["http://zotero.org/groups/945096/items/64HZKA2M"],"itemData":{"id":990,"type":"article-journal","title":"Full-scale biological treatment of nitrate and perchlorate for potable water production","container-title":"Journal AWWA","page":"30-40","volume":"109","issue":"5","author":[{"family":"Webster","given":"T.D."},{"family":"Litchfield","given":"M.H."}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The treatment process, however, can result in removal of co-occurring contaminants such as nitrate (Upadhyaya et al., 2015; Webster and Crowley, 2010; Webster and Lichfield, 2017).

Reverse Osmosis.

Reverse osmosis is a membrane filtration process that physically removes perchlorate ions from drinking water. This process separates a solute such as perchlorate ions from a solution by forcing the solvent to flow through a membrane at a pressure greater than the normal osmotic pressure. The membrane is semi-permeable, transporting different molecular species at different rates. Water and low-molecular weight solutes pass through the membrane and are removed as permeate, or filtrate. Dissolved and suspended solids are rejected by the membrane and are removed as concentrate or reject. This technique does not destroy the perchlorate ion and, therefore, creates a subsequent need for disposal or treatment of perchlorate-contaminated waste (the concentrate).

Membranes may remove ions from feed water by a sieving action (called steric exclusion), or by electrostatic repulsion of ions from the charged membrane surface. Across multiple bench- and pilot-scale studies, reverse osmosis membranes consistently achieve perchlorate removal greater than 80 percent and up to 98 percent [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"edXX3GgQ","properties":{"formattedCitation":"(Liang, Scott, Palencia, & Bruno, 1998; Nam et al., 2005; Yoon, Amy, & Yoon, 2005; Yoon, Yoon, Amy, & Her, 2005)","plainCitation":"(Liang, Scott, Palencia, & Bruno, 1998; Nam et al., 2005; Yoon, Amy, & Yoon, 2005; Yoon, Yoon, Amy, & Her, 2005)","noteIndex":0},"citationItems":[{"id":985,"uris":["http://zotero.org/groups/945096/items/IQVVPD73"],"uri":["http://zotero.org/groups/945096/items/IQVVPD73"],"itemData":{"id":985,"type":"paper-conference","title":"Investigation of Treatment Options for Perchlorate Removal.","publisher":"La Verne, CA: Metropolitan Water District of Southern California","publisher-place":"San Diego, CA","event":"AWWA Water Quality Technology Conference","event-place":"San Diego, CA","author":[{"family":"Liang","given":"S."},{"family":"Scott","given":"K.N."},{"family":"Palencia","given":"L.S."},{"family":"Bruno","given":"J."}],"issued":{"date-parts":[["1998"]]}}},{"id":986,"uris":["http://zotero.org/groups/945096/items/YHEV76YW"],"uri":["http://zotero.org/groups/945096/items/YHEV76YW"],"itemData":{"id":986,"type":"paper-conference","title":"Perchlorate Rejection by High-Pressure Membranes and Brine Stream Treatment by Chemical and Biological Processes.","publisher-place":"Phoenix, AZ","event":"American Water Works Association Membrane Technology Conference","event-place":"Phoenix, AZ","author":[{"family":"Nam","given":"S."},{"family":"Kim","given":"S."},{"family":"Choi","given":"H."},{"family":"Yoon","given":""},{"family":"Silverstein","given":"J."},{"family":"Amy","given":"G."}],"issued":{"date-parts":[["2005"]]}}},{"id":992,"uris":["http://zotero.org/groups/945096/items/HPHVBSWB"],"uri":["http://zotero.org/groups/945096/items/HPHVBSWB"],"itemData":{"id":992,"type":"article-journal","title":"Transport of target anions, chromate (Cr (VI)), arsenate (As (V)), and perchlorate (ClO4), through RO, NF, and UF membranes.","container-title":"Water Science and Technology","page":"327-334","volume":"51","issue":"6-7","author":[{"family":"Yoon","given":"J."},{"family":"Amy","given":"G."},{"family":"Yoon","given":"Y."}],"issued":{"date-parts":[["2005"]]}}},{"id":991,"uris":["http://zotero.org/groups/945096/items/IIJW6E8Q"],"uri":["http://zotero.org/groups/945096/items/IIJW6E8Q"],"itemData":{"id":991,"type":"article-journal","title":"Determination of perchlorate rejection and associated inorganic fouling (scaling) for reverse osmosis and nanofiltration membranes under various operating conditions","container-title":"Journal of Environmental Engineering","page":"726-733","author":[{"family":"Yoon","given":"J."},{"family":"Yoon","given":"Y."},{"family":"Amy","given":"G."},{"family":"Her","given":"N."}],"issued":{"date-parts":[["2005",5]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. While water quality affects process design (e.g., recovery rate, cleaning frequency, and antiscalant selection), it has relatively little effect on perchlorate removal effectiveness of reverse osmosis membranes. Reverse osmosis generates a relatively large concentrate stream, which will contain perchlorate as well as other rejected dissolved solids, which will require disposal. The large concentrate stream also means less treated water is available for distribution (e.g., 70 to 85 percent of source water), which is a disadvantage for systems with limited water supply. Because reverse osmosis can increase the corrosivity of the treated water, it may require post-treatment or blending with bypass water. Reverse osmosis can, however, remove co-occurring contaminants including arsenic and chromium-VI (Amy, Yoon, and Amy, 2005).

B. What are the Small System Compliance Technologies?

The EPA is proposing the SSCT shown in [REF _Ref529958951 \h]. The table shows which of the BAT listed above are also affordable for each small system size category listed in Section 1412(b)(4)(E)(ii) of the SDWA. The Agency identified these technologies based on an analysis of treatment effectiveness and affordability [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"J9AlL73G","properties":{"formattedCitation":"(USEPA, 2018a)","plainCitation":"(USEPA, 2018a)","noteIndex":0},"citationItems":[{"id":1210,"uris":["http://zotero.org/groups/945096/items/QBLZF9AR"],"uri":["http://zotero.org/groups/945096/items/QBLZF9AR"],"itemData":{"id":1210,"type":"article","title":"Best Available Technologies and Small System Compliance

Technologies for Perchlorate in Drinking Water.","publisher":"EPA ***-*-*-****","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Table X-[SEQ Table * ARABIC \s 1]: Proposed SSCT for Perchlorate Removal

System Size (Population Served)	Ion Exchange	Biological Treatment	Reverse Osmosis	Point-of-Use Reverse Osmosis
25-500	Yes	No	No	Yes
501-3,300	Yes	Yes	Yes	Yes
3,301-10,000	Yes	Yes	Yes	Not applicable[a]

a. For perchlorate, the EPA has determined that implementing and maintaining this option for systems larger than 3,300 people (greater than 1 MGD design flow) is likely to be impractical.

The SSCT listed in [REF _Ref529958951 \h] include a point-of-use (POU) version of reverse osmosis in addition to the ion exchange, biological treatment and reverse osmosis technologies described in the previous section. This technology can be used by small systems to comply with the proposed MCL and, therefore, meets the effectiveness requirement for an SSCT. For perchlorate removal, NSF/ANSI Standard 58: Reverse Osmosis Drinking Water Treatment Systems includes a protocol that requires a reverse osmosis unit to be able to reduce perchlorate from a challenge level of 130 µg/L to a target level of 4 µg/L (NSF, 2004). Organizations (e.g., NSF International, Underwriters Laboratories, Water Quality Association) provide third-party testing and certification that POU devices meet drinking water treatment standards. There are no perchlorate certification standards for other types of POU devices such as those using ion exchange media.

The operating principle for POU reverse osmosis devices is the same as centralized reverse osmosis: steric exclusion and electrostatic repulsion of ions from the charged membrane surface. In addition to a reverse osmosis membrane for dissolved ion removal, POU reverse osmosis devices often have a sediment pre-filter and a carbon filter in front of the reverse osmosis membrane, a 3- to 5-gallon treated water storage tank, and a carbon filter between the tank and the tap.

The EPA identified the SSCT using the affordability criteria methodology it developed for drinking water rules [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"LHgBHn5b","properties":{"formattedCitation":"(USEPA, 1998)","plainCitation":"(USEPA, 1998)","noteIndex":0},"citationItems":[{"id":1215,"uris":["http://zotero.org/groups/945096/items/399QNBY4"],"uri":["http://zotero.org/groups/945096/items/399QNBY4"],"itemData":{"id":1215,"type":"article","title":"Variance Technology Findings for Contaminants Regulated Before 1996","publisher":"EPA 815–R– 98–003. September","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["1998"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The analysis method is a comparison of estimated incremental household costs for perchlorate treatment to an expenditure margin, which is the difference between baseline household water costs and a threshold equal to 2.5% of median household income. [REF _Ref529959037 \h] shows the expenditure margins derived for the analysis. These margins show the cap on affordable incremental annual expenditures.

Table X-[SEQ Table * ARABIC \s 1]: Expenditure Margins for SSCT Affordability Analysis

System Size (Population Served)	Median Household Income[a] (a)	Affordability Threshold[b] (b) = 2.5% x a	Baseline Water Cost[c] (c)	Expenditure Margin (d) = b - c
25-500	$52,791	$1,320	$341	$979
501-3,300	$51,093	$1,277	$395	$883
3,301-10,000	$55,975	$1,399	$412	$987

Source: *Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water* [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"2scXqyv0","properties":{"formattedCitation":"(USEPA, 2018a)","plainCitation":"(USEPA, 2018a)","noteIndex":0},"citationItems":[{"id":1210,"uris":["http://zotero.org/groups/945096/items/QBLZF9AR"],"uri":["http://zotero.org/groups/945096/items/QBLZF9AR"],"itemData":{"id":1210,"type":"article","title":"Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water.","publisher":"EPA ***-*-*-****","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

a. MHI based on U.S. Census 2010 American Community Survey (ACS) 5-year estimates [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"x096Tc8Y","properties":{"formattedCitation":"(U.S. Census Bureau, 2010)","plainCitation":"(U.S. Census Bureau, 2010)","noteIndex":0},"citationItems":[{"id":1225,"uris":["http://zotero.org/groups/945096/items/WJ35QNBT"],"uri":["http://zotero.org/groups/945096/items/WJ35QNBT"],"itemData":{"id":1225,"type":"article","title":"American Community Survey, 5-year Estimates (2006-2010)","author":[{"family":"U.S. Census Bureau","given":""}],"issued":{"date-parts":[["2010"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] stated in 2010 dollars, adjusted to 2017 dollars using the CPI (for all items) for areas under 50,000 persons [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"7Rg9m81J","properties":{"formattedCitation":"(Bureau of Labor Statistics (BLS), 2018b)","plainCitation":"(Bureau of Labor Statistics (BLS), 2018b)","noteIndex":0},"citationItems":[{"id":1226,"uris":["http://zotero.org/groups/945096/items/GTI7H6YK"],"uri":["http://zotero.org/groups/945096/items/GTI7H6YK"],"itemData":{"id":1226,"type":"article","title":"CPI--All Urban Consumers (all items), for areas under 50,000 persons","author":[{"family":"Bureau of Labor Statistics (BLS)","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

b. Affordability threshold equals 2.5 percent of MHI.

c. Household water costs derived from 2006 Community Water System Survey [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"fS2Ibu6t","properties":{"formattedCitation":"(USEPA, 2009c)","plainCitation":"(USEPA, 2009c)","noteIndex":0},"citationItems":[{"id":163,"uris":["http://zotero.org/groups/945096/items/DZNAAV6M"],"uri":["http://zotero.org/groups/945096/items/DZNAAV6M"],"itemData":{"id":163,"type":"article","title":"2006 Community Water System Survey - Volume II: Detailed Tables and Survey Methodology","URL":"https://www.epa.gov/dwstandardsregulations/community-water-system-survey","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2009",5]]},"accessed":{"date-parts":[["2018",8,17]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], based on residential revenue per connection within each size category, adjusted to 2017 dollars based on the CPI (for all items) for areas under 50,000 persons.

[REF _Ref529959069 \h] shows the estimates of per-household costs by treatment technology and size category generated using the treatment cost method described in section XII.B as well as *Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water* [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"z6GYvRh1","properties":{"formattedCitation":"(USEPA, 2018a)","plainCitation":"(USEPA, 2018a)","noteIndex":0},"citationItems":[{"id":1210,"uris":["http://zotero.org/groups/945096/items/QBLZF9AR"],"uri":["http://zotero.org/groups/945096/items/QBLZF9AR"],"itemData":{"id":1210,"type":"article","title":"Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water.","publisher":"EPA ***-*-*-****","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] and *Technologies and Costs for Treating Perchlorate-Contaminated Waters* [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"18aKvRLD","properties":{"formattedCitation":"(USEPA, 2018f)","plainCitation":"(USEPA, 2018f)","noteIndex":0},"citationItems":[{"id":147,"uris":["http://zotero.org/groups/945096/items/VUJUPN7L"],"uri":["http://zotero.org/groups/945096/items/VUJUPN7L"],"itemData":{"id":147,"type":"article","title":"Technologies and Costs for Treating Perchlorate-Contaminated Waters","publisher":"EPA ***-*-*-

****","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Costs in bold font do not exceed the corresponding expenditure margin and, therefore, meet the SSCT affordability criterion. Therefore, the EPA has determined that there are affordable small system compliance technologies available and the Agency is not proposing any variance technologies.

Table X-[SEQ Table * ARABIC \s 1]: Annual Incremental Cost Estimates for SSCT Affordability Analysis

System Size (Population Served)	Ion Exchange	Biological Treatment	Reverse Osmosis	Point-of-Use Reverse Osmosis
25-500	**$378 to $610**	$2,146 to $3,709	$2,272 to $2,671	**$265 to $271**
501-3,300	**$98 to $148**	**$324 to $566**	**$561 to $688**	**$250 to $251**
3,301-10,000	**$104 to $153**	**$211 to $315**	**$431 to $493**	Not applicable[a]

Source: *Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water* [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"8y1WSJT4","properties":{"formattedCitation":"(USEPA, 2018a)","plainCitation":"(USEPA, 2018a)","noteIndex":0},"citationItems":[{"id":1210,"uris":["http://zotero.org/groups/945096/items/QBLZF9AR"],"uri":["http://zotero.org/groups/945096/items/QBLZF9AR"],"itemData":{"id":1210,"type":"article","title":"Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water.","publisher":"EPA ***-*-*-****","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], which describes the different WBS model input assumptions that result in ranges of per-household costs shown; bold font indicates cost estimates that do not exceed the corresponding expenditure margin.
a. For perchlorate, the EPA has determined that implementing and maintaining a POU program for systems larger than 3,300 people (greater than 1 MGD design flow) is likely to be impractical.

XI. Rule Implementation and Enforcement

A. What are the Requirements for Primacy?

This section describes the regulations and other procedures and policies primacy entities must adopt, or have in place, to implement the proposed perchlorate rule. States must continue to meet all other conditions of primacy in 40 CFR part 142. Section 1413 of the SDWA establishes requirements that primacy entities (States or Indian Tribes) must meet to maintain primary enforcement responsibility (primacy) for its public water systems. These include: (1) Adopting drinking water regulations that are no less stringent than federal NPDWRs in effect under sections 1412(a) and 1412(b) of the Act, (2) Adopting and implementing adequate procedures for enforcement, (3) Keeping records and making reports available on activities that the EPA requires by regulation, (4) Issuing variances and exemptions (if allowed by the State) under conditions no less stringent than allowed by SDWA Sections 1415 and 1416, and (5) Adopting and being capable of implementing an adequate plan for the provision of safe drinking water under emergency situations.

40 CFR part 142 sets out the specific program implementation requirements for States to obtain primacy for the Public Water Supply Supervision Program, as authorized under section 1413 of the Act.

To implement the perchlorate rule, States would be required to adopt revisions at least as stringent as the proposed provisions in 40 CFR 141.6 (Effective Dates); 40 CFR 141.23 (Inorganic chemical sampling and analytical requirements); 40 CFR 141.51 (Maximum contaminant level goals for inorganic contaminants); 40 CFR 141.60 (Effective Dates); 40 CFR 141.62 (Maximum contaminant levels for inorganic contaminants); Appendix A to Subpart O ([Consumer Confidence Report] Regulated contaminants); Appendix A to Subpart Q (NPDWR violations and other situations requiring public notice); Appendix B to Subpart Q (Standard health effects language for public notification); and 40 CFR 142.62 (Variances and exemptions from the maximum contaminant levels for organic and inorganic contaminants). Under 40 CFR 142.12(b), all primacy States/territories/tribes would be required to submit a revised program to the EPA for approval within two years of promulgation of any final perchlorate NPDWR or could request an extension of up to two years in certain circumstances.

B. What are the State Record Keeping Requirements?

The current regulations in 40 CFR 142.14 require States with primary enforcement responsibility (i.e., primacy) to keep records of analytical results to determine compliance, system inventories, sanitary surveys, State approvals, vulnerability and waiver determinations, monitoring requirements, monitoring frequency decisions, enforcement actions, and the issuance of variances and exemptions. The State record keeping requirements remain unchanged and would apply to perchlorate as with any other regulated contaminant.

C. What are the State Reporting Requirements?

Currently, States must report to the EPA information under 40 CFR 142.15 regarding violations, variances and exemptions, enforcement actions and general operations of State public water supply programs. The State reporting requirements remain unchanged and would apply to perchlorate as with any other regulated contaminant. However, the perchlorate MCL could result in a greater frequency of reporting by certain states. See discussion of Paperwork Reduction Act compliance in Section XVI for more information.

XII. Health Risk Reduction Cost Analysis

Section 1412(b)(3)(C) of the 1996 Amendments to the SDWA requires the EPA to prepare a Health Risk Reduction and Cost Analysis (HRRCA) in support of any NPDWR that includes an MCL. This section addresses the HRRCA requirements as indicated:

- Quantifiable and non-quantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level (Sections XII.C and XII.D);
- Quantifiable and non-quantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the MCL, excluding benefits resulting from compliance with other proposed or promulgated regulations (Section XII.C);
- Quantifiable and non-quantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the MCL, including monitoring, treatment, and other costs, and excluding costs resulting from compliance with other proposed or promulgated regulations (Section XII.B and XII.D);
- The incremental costs and benefits associated with each alternative MCL considered (Section XII.D);

- The effects of the contaminant on the general population and on groups within the general population, such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other sensitive populations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population (Section XII.C and Section III);
- Any increased health risk that may occur as the result of compliance, including risks associated with co-occurring contaminants (Section XII.C); and
- Other relevant factors, including the quality and extent of the information, the uncertainties in the analysis, and factors with respect to the degree and nature of the risk (Section XII.E).

A. Identifying Affected Entities

If the EPA issues a final NPDWR for perchlorate, it would affect the following entities: CWSs and NTNCWSs that must meet the proposed MCL and monitoring and reporting requirements; and primacy agencies that must adopt and enforce the MCL as well as the monitoring and reporting requirements. All of these entities would incur costs, including administrative costs, monitoring and reporting costs, and – in a limited number of cases – costs to reduce perchlorate levels in drinking water to meet the proposed MCL using treatment or nontreatment options. Section B below summarizes the method the EPA used to estimate these costs.

The systems that reduce perchlorate concentrations will reduce associated health risks. The EPA developed a method to estimate the potential benefits of reduced perchlorate exposure among the service populations of systems with elevated baseline perchlorate levels. Section C below summarizes this method used to estimate these benefits.

Section D below provides the cost and benefit estimates. The EPA prepared the Health Risk Reduction Cost Analysis of the Proposed Perchlorate Rule (USEPA, 2019a), which is available in the docket for the proposed rule. Section XIII summarizes and discusses key uncertainties in the cost and benefit analyses.

B. Method for Estimating Costs

Some costs associated with an NPDWR are incurred by all CWS and NTNCWS (e.g. monitoring and reporting) while others are only incurred by systems with perchlorate levels exceeding the MCL. The EPA estimated costs for CWS and NTNCWS to monitor and report perchlorate levels and also estimated the costs for a subset of public water systems with perchlorate levels greater than the proposed MCL to install and operate treatment. The EPA assumed that affected water systems would adopt ion exchange treatment because it is the most cost-effective treatment option and easy to operate on a 'throw-away' basis. If site-specific nontreatment options are available and lower cost, then this assumption might overstate costs. The EPA also estimated the costs for States and other primacy agencies to assure systems implement the rule and to report information to the EPA.

The EPA estimated initial costs for all CWS and NTNCWS operators to read and understand the rule and provide training to their staff to implement the proposed rule. The EPA also estimated the recurring costs for all CWS and NTNCWS operators to conduct monitoring, report results, and apply for waivers. For the purpose of these estimates, the EPA assumed that both small and large systems would require the same amount of time to read the rule, apply for a waiver, and collect a water sample but that it would take large systems twice as long to provide initial training to their staff. Table XII-1 summarizes the frequency and labor hour assumptions for this analysis.

Table XII-1: Labor Hours for Drinking Water Systems Administrative and Monitoring Requirements

Activity	Frequency	Small System Hours	Large System Hours
Read the rule	one time per system	4	4
Provide initial training	one time per system	16	32
Apply to State for monitoring waiver	once every 9 years per eligible system	16	16
Collect a single finished water sample[1]	per monitoring event	1	1

Source (USEPA, 2000a). The EPA's cost analysis reflects full MCL compliance and therefore the EPA did not estimate Tier 1 notification costs.
1. The estimate is per sample. Therefore, a system conducting a year of quarterly monitoring at three entry points incurs a total of 12 hours of labor to complete the task (3 entry points x 4 samples x 1 hour per sample).

Systems will incur monitoring costs over the analysis period. The EPA estimated monitoring frequency based on the proposed initial monitoring requirements, the standard monitoring framework requirements for inorganic contaminants, and the proposed implementation schedule. The estimated number of monitoring samples over the analysis period shown in Table XII-2 reflect the following phases:

1. Initial monitoring; four quarterly samples at every CWS and NTNCWS entry point.

2. Preliminary regular monitoring before waiver application: three regular monitoring samples for every CWS and NTNCWS entry point (collected annually at surface water system entry points and triennially at ground water system entry points).

3. Long-term monitoring at either (a) regular monitoring frequency for entry points at systems not granted waivers (60% of surface water system and 10% of ground water systems), or (b) reduced monitoring frequency for entry points at systems receiving waivers from primacy agencies (40% of surface water systems and 90% of ground water systems), which is one sample during every nine-year compliance monitoring cycle.

Table XII-2: Estimates of Compliance Monitoring Samples by Phase and System Type, Size, and Source Water

Monitoring Phase (sampling frequency)	System Type, Size, and Source Water	Number of Entry Points[1]	Aggregate Samples[2]
1. Initial monitoring (4 quarterly samples in one year)	All CWS and NTNCWS	92,656	370,624
2. Preliminary regular monitoring (3 annual entry point samples for surface water systems and 3 triennial entry point samples for ground water systems)	All CWS and NTNCWS	92,654	277,962
3a. Long-term monitoring, no waiver (annual entry point samples)	60% of large surface water CWS	3,324	86,424
	60% of small surface water CWS and all surface water NTNCWS	6,064	139,472
3a. Long-term monitoring, no waiver (triennial entry point samples)	10% of large ground water CWS	680	4,080
	10% of small ground water CWS and all ground water NTNCWS	7,021	35,105
3b. Long-term monitoring, waiver (1 sample every 9 years)	40% of large surface water CWS	2,216	4,432
	40% of small surface water CWS and all surface water NTNCWS	4,043	8,086
3b. Long-term monitoring, waiver (1 sample every 9 years)	90% of large ground water CWS	6,117	12,234
	90% of small ground water CWS and all ground water NTNCWS	63,189	63,189

Source: Perchlorate Benefit-Cost Analysis Spreadsheet available in the proposed rule docket (EPA-HQ-OW-2018-0780).

1. The EPA estimated a total of 92,656 entry points based on the total number of potentially affected systems in SDWIS/FED and the average number of entry points per system in the UCMR 1 data by size category and source water. The initial monitoring phase includes all entry points. The EPA assumed that the two entry points with MCL exceedances at the proposed MCL of 56 µg/L would continue to take quarterly samples for the duration of the analysis period, for a total of 232 samples. Thus, they are excluded from the estimates for the subsequent phases of regular and long-term monitoring. Primacy agencies may, however, allow monitoring to return to a regular schedule if treatment process operation can reliably and consistently reduce perchlorate below the MCL.

2. For Phase 3, the estimate of aggregate samples is the product of the number of entry points and the frequency of sampling during the remaining years of the analysis period. For example, large surface water CWS without a waiver conduct long-term annual monitoring for 26 years because they complete preliminary regular monitoring in year 9. In contrast, large ground water CWS without a waiver begin long-term triennial monitoring in year 16 because their preliminary regular monitoring phase lasts for 9 years (3 triennial samples) instead of 3 years (3 annual samples). The estimates also reflect schedule differences by size because large CWS begin monitoring schedules three years earlier than small CWS and all NTNCWS.

To estimate costs to CWSs and NTNCWSs associated with time spent on compliance monitoring and other administrative costs, the EPA generally uses the labor rate[13] for full-time treatment plant operators in CWSs from USEPA [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"5g8IJ6Eh","properties":{"formattedCitation":"(2011)","plainCitation":"(2011)","noteIndex":0},"citationItems":[{"id":992,"uris":["http://zotero.org/groups/945096/items/FHCVSMRC"],"uri":["http://zotero.org/groups/945096/items/FHCVSMRC"],"itemData":{"id":992,"type":"article","title":"Labor Cost for National Drinking Water

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[13] Updated to 2017$ using the BLS Employment Cost Index for Total Compensation for Private industry workers in Utilities.

Rules","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2011"]]}},"suppress-author":true}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], which vary based on the size of the system. The EPA calculated a weighted average fully loaded hourly wage rate for water systems of $34.71.

Additionally, the EPA assumed that systems will incur an average analytical cost of $64 per sample, which is the average cost per sample obtained from multiple laboratories for perchlorate quantitation using Method 314.0.

To estimate treatment cost, the EPA utilized the occurrence data described in Section VI to estimate the number of system entry points that exceed the proposed and alternative MCLs. The EPA estimated costs that those water systems would incur to install and maintain treatment using its work breakdown structure (WBS) cost estimating models. The WBS models are spreadsheet-based engineering models for individual treatment technologies, linked to a central database of component unit costs. The WBS approach involves breaking a process down into discrete components for the purpose of estimating costs and produce a comprehensive assessment of the capital and operating requirements for a treatment system[14]. The EPA used the WBS models to generate total capital and O&M cost estimates for each technology and nontreatment option for up to 49 different system flow rates. The EPA generated separate

[14] The document *Technologies and Costs for Treating Perchlorate-Contaminated Waters* (USEPA, 2018c) contains more complete discussion of the WBS models and the cost estimating approach.

estimates that correspond to different water sources (groundwater or surface water), three different cost levels (low, mid, and high), and different technology-specific scenarios (e.g., 105,000 or 170,000 bed volumes for ion exchange). The EPA used the mid-cost estimates for ion exchange to generate expected costs for all entry points requiring perchlorate removal. This technology cost-effectively removes perchlorate, but its ability to remove co-occurring contaminants depends on influent characteristics and process design. Therefore, the EPA did not assume that treatment might result in ancillary quantifiable or non-quantifiable benefits of removing co-occurring ions such as nitrate. Treatment costs include waste disposal for spent resin, but do not include post-treatment costs for corrosion control because blending rates at most entry points should not result in much chloride addition or changes in corrosivity.

For purposes of estimating the costs and benefits, the EPA assumed that CWSs and NTNCWSs in California and Massachusetts would not incur additional cost or realize benefits because these States currently regulate perchlorate at a more stringent level than the proposed MCL and alternative MCL. For each entry point in the UCMR 1 dataset outside of these two States, the EPA compared the maximum observed perchlorate concentration to the MCL to identify those that have an exceedance of the proposed MCL. The EPA assumed that these entry points would incur costs for an additional confirmation sample and would need to implement treatment to meet the MCL. For each entry point, the EPA estimated the design flow and the average flow by service populations based on the Agency's prior analysis of the relationships between these values (USEPA, 2000b). The Agency assumed blending of treated water and untreated water would be used to meet an average treatment target equal to 80 percent of the MCL (for an MCL of 56 μg/L the blending target would be 45 μg/L) given a 95 percent removal effectiveness until perchlorate breakthrough. The Agency applied the capital cost and O&M cost curves from the WBS models to the design and average flows adjusted for blending. When small systems in the UCMR 1 sample incurred treatment costs, the EPA extrapolated the costs on a per capita basis to the estimate of national population exposure derived using the small system population sampling weights.

For the primacy agencies that will implement and enforce the rule (including 49 States, one tribal nation and 5 territories), the EPA estimated upfront costs incurred during the three years between rule promulgation and the effective date to read and understand the rule, adopt regulatory changes, and provide training to CWSs and NTNCWSs and Agency staff. Primacy agencies will also have recurring costs to review waiver applications and monitoring reports. Table XII-3 summarizes the labor hour assumptions for these activities. The EPA requests comments on these assumptions.

Table XII-3: Labor Hours for Primacy Agency Administrative Requirements

Activity	Frequency	Hours
Read and understand the rule, adopt regulatory changes[1]	one time per Agency	416
Provide initial training and assistance to water systems[2]	total per Agency	2,080
Provide initial training to staff[2]	total per Agency	250
Review waiver applications	once every 9 years per eligible system	8
Review monitoring reports	per monitoring event	1

Source (USEPA, 2000a)

1. The EPA assumed that two States that already regulate perchlorate in drinking water would not incur the incremental burdens in this table to regulate perchlorate under the proposed rule because they already incur baseline costs for perchlorate regulation including monitoring costs. The Agency assumed, however, that the two States would incur an average of 40 hours to confirm that their existing requirements are at least as protective as the proposed rule.
2. The EPA assumed that all training hours occur in a single year, although the hours may actually occur over time. The total hour estimates are average values across States.

State labor rates are based on the mean hourly wage rate from Bureau of Labor Statistics (BLS) Standard Occupational Classification code 19-2041 (State Government –Environmental Scientists and Specialists, Including Health). Wages are loaded using a factor calculated from the BLS Employer Costs for Employee Compensation report [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"C1A8zUkj","properties":{"formattedCitation":"(Bureau of Labor Statistics (BLS), 2016 Table 3)","plainCitation":"(Bureau of Labor Statistics (BLS), 2016 Table 3)","noteIndex":0},"citationItems":[{"id":984,"uris":["http://zotero.org/groups/945096/items/L8X3BDZ9"],"uri":["http://zotero.org/groups/945096/items/L8X3BDZ9"],"itemData":{"id":984,"type":"webpage","title":"Employer Cost for Employee Compensation -- September 2016","author":[{"literal":"Bureau of Labor Statistics (BLS)"}],"issued":{"date-parts":[["2016"]]}},"label":"book","suffix":"Table 3"}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], for a fully loaded hourly wage rate for States of $50.67. The EPA requests comments on these labor rate assumptions.

The proposed rule provides three years between the effective dates and compliance dates for systems. For the purpose of estimating costs, the EPA assumed that large CWSs would phase in administrative costs, including initial monitoring, and upfront administrative costs uniformly over the 3 years following the effective date (i.e., years 4 to 6 of the analysis period). Similarly, the EPA assumed that small CWSs and NTNCSs will phase in these costs over the subsequent three-year period (i.e., years 7 to 9 of the analysis period). The EPA assumed that, within these periods, all systems would conduct initial monitoring – one year of quarterly monitoring to determine whether perchlorate concentrations are consistently and reliably below the proposed MCL. Thereafter, systems with MCL exceedances would continue to monitor quarterly, while systems below the MCL that obtain waivers will monitor annually for three years (surface water systems) or triennially for 9 years (ground water systems), then incur costs for a waiver application. Thereafter, these systems will continue reduced monitoring - once every nine years - under subsequent waivers. Systems that are below the MCL without waivers will monitor once per year (surface water systems) or once every three years (groundwater). Consistent with [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"mnzEXxZK","properties":{"formattedCitation":"(USEPA, 2008b)","plainCitation":"(USEPA, 2008b)","dontUpdate":true,"noteIndex":0},"citationItems":[{"id":998,"uris":["http://zotero.org/g roups/945096/items/QSXYHBID"],"uri":["http://zotero.org/groups/945096/items/QSXYHBID"],"itemData":{"id":998,"type":"article","title":"Draft Information Collection Request for the Disinfectants/Disinfection Byproducts, Chemical, and Radionuclides Rule","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2008",6]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], the EPA assumed that 90% of groundwater and 40% of surface water systems that have all entry points below the MCL would obtain waivers.

The EPA estimated the costs over a 35-year analysis period, which includes a 3-year period prior to the effective date to allow for State rule adoption activities, a 3-year period after the effective date to allow initial monitoring among large CWSs, and a 3-year period after that to allow initial monitoring for small CWSs and NTNCWSs. Evaluating costs over 35 years covers a full life cycle of the capital investments that large systems make in the 6^{th} year; the WBS estimates of composite useful life of the equipment and infrastructure investment is approximately 30 years. The EPA assumed that treatment modifications will be completed in the final year of the initial monitoring period (i.e., year 6 of the analysis for large CWSs and year 9 for small CWSs and NTNCWSs). The EPA calculated the present value of total costs in each year of the analysis period and discounted to year 1 using both a 3% and 7% discount rate and annualized total present value of costs at the same rates over 35 years to obtain a constant total annual cost estimate to compare to total annual benefits.

Water systems typically recover costs through increased household rates, resulting in increased costs at the household level[15]. To calculate the magnitude of the cost increase for systems that exceed the proposed MCL or alternative MCL, the EPA first estimated the number of households that may incur costs as a result of the rule based on the population served by affected CWSs and NTNCWSs and the average household size [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"Q6RKolIZ","properties":{"formattedCitation":"(U.S. Census Bureau, 2017b)","plainCitation":"(U.S. Census Bureau, 2017b)","noteIndex":0},"citationItems":[{"id":1000,"uris":["http://zotero.org/groups/945096/items/CGU3LT9N"],"uri":["http://zotero.org/groups/945096/items/CGU3LT9N"],"itemData":{"id":1000,"type":"article","title":"Average Household Size of Occupied Housing Units by Tenure. American Community Survey 1-Year Estimates: Table B25010","author":[{"family":"U.S. Census Bureau","given":""}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The EPA divided the total annual system-level costs by the number of households served by the system.

C. Method for Estimating Benefits

The EPA has taken an approach in evaluating the benefits for perchlorate that is consistent with the SAB's recommendations for the methodology to inform the MCLG for

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[15] For systems with monitoring costs only, household-level costs will be negligible.

perchlorate. This approach involves a) using a BBDR model to estimate the impact of perchlorate on maternal thyroid hormone levels during the first trimester of pregnancy, and b) using a dose-response function from the epidemiological literature to model the relationship between altered maternal thyroid hormone levels and offspring IQ. Currently available science has limited this quantitative benefits assessment to the relationship between perchlorate and IQ. Given that alterations in thyroid hormones have been associated with other adverse outcomes, including reproductive outcomes (Alexander et al., 2017; Hou et al., 2016; Maraka et al., 2016) and effects on cardiovascular systems (Asvold et al., 2012; Sun et al., 2017) there are likely non-quantified benefits of risk reductions for other endpoints or reduced exposure to co-occurring contaminants, which are addressed below. Uncertainties regarding the quantifiable benefits are also addressed below.

The population impacted by the rule for which benefits can be quantified is specific to live births from mothers who were served by a CWS or NTNCWS with perchlorate concentrations above the potential MCLs. To determine the nationwide population of children that will experience a quantifiable benefit of avoided IQ decrements from reducing maternal perchlorate exposure during pregnancy, the EPA first estimated the total population being served by systems above the MCL based on data from UCMR 1. The EPA then multiplied the total population served for each affected CWS and NTNCWS by the proportion of women of childbearing age (aged 15-44) in the US, which is 19.7 percent [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"rCNbGglo","properties":{"formattedCitation":"(U.S. Census

Bureau, 2017a)","plainCitation":"(U.S. Census Bureau, 2017a)","noteIndex":0},"citationItems":[{"id":189,"uris":["http://zotero.org/groups/945096/items/ZM7S6H44"],"uri":["http://zotero.org/groups/945096/items/ZM7S6H44"],"itemData":{"id":189,"type":"article","title":"Annual estimates of the resident population by single year of age and sex for the United States: April 1, 2010 to July 1, 2016.","URL":"https://www.census.gov/data/datasets/2016/demo/popest/nation-detail.html#ds","author":[{"literal":"U.S. Census Bureau"}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The number of women of child-bearing age for each entry point was then multiplied by the annual number of live births in the US, or 62 births per 1,000 women (6.2 percent) [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"7XfZyKhY","properties":{"formattedCitation":"(Martin, Hamilton, & Osterman, 2017)","plainCitation":"(Martin, Hamilton, & Osterman, 2017)","noteIndex":0},"citationItems":[{"id":186,"uris":["http://zotero.org/groups/945096/items/MY6LPDKD"],"uri":["http://zotero.org/groups/945096/items/MY6LPDKD"],"itemData":{"id":186,"type":"article","title":"Births in the United States, 2016. NCHS Data Brief No. 287","URL":"https://www.cdc.gov/nchs/data/databriefs/db287.pdf","author":[{"family":"Martin","given":"J.A."},{"family":"Hamilton","given":"B.E."},{"family":"Osterman","given":"M.J.K"}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

The EPA used a two-step dose-response model to estimate health benefits of a reduction in perchlorate exposure as a result of regulating perchlorate in drinking water not to exceed the proposed MCL of 56 μg/L and alternative MCLs of 18 μg/L and 90 μg/L. The first step relates changes in perchlorate to changes in maternal free-thyroxine (fT4) during the first trimester of pregnancy using the EPA's BBDR model. Because the dose-response relationship between perchlorate exposure and maternal fT4 is dependent on maternal iodine intake status, this first-step analysis is repeated for several categories of iodine intake. For the BBDR simulations, the EPA used the 90th percentile ingestion rate to be consistent with the MCLG modeling approach, which may overstate the exposure in the simulation.

The second step of the dose-response model subsequently relates the predicted changes in maternal fT4 from the BBDR model to changes in child IQ using the function estimated in the EPA independent analysis of the [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"iqyVRL6z","properties":{"formattedCitation":"(Korevaar et al., 2016)","plainCitation":"(Korevaar et al., 2016)","dontUpdate":true,"noteIndex":0},"citationItems":[{"id":43,"uris":["http://zotero.org/groups/945096/items/B968J6XI"],"uri":["http://zotero.org/groups/945096/items/B968J6XI"],"itemData":{"id":43,"type":"article-journal","title":"Association of maternal thyroid function during early pregnancy with offspring IQ and brain morphology in childhood: a population-based prospective cohort study","container-title":"The Lancet Diabetes & Endocrinology","page":"35-43","volume":"4","issue":"1","source":"ScienceDirect","abstract":"SummaryBackground\nThyro

id hormone is involved in the regulation of early brain development. Since the fetal thyroid gland is not fully functional until week 18–20 of pregnancy, neuronal migration and other crucial early stages of intrauterine brain development largely depend on the supply of maternal thyroid hormone. Current clinical practice mostly focuses on preventing the negative consequences of low thyroid hormone concentrations, but data from animal studies have shown that both low and high concentrations of thyroid hormone have negative effects on offspring brain development. We aimed to investigate the association of maternal thyroid function with child intelligence quotient (IQ) and brain morphology.\nMethods\nIn this population-based prospective cohort study, embedded within the Generation R Study (Rotterdam, Netherlands), we investigated the association of maternal thyroid function with child IQ (assessed by non-verbal intelligence tests) and brain morphology (assessed on brain MRI scans). Eligible women were those living in the study area at their delivery date, which had to be between April 1, 2002, and Jan 1, 2006. For this study, women with available serum samples who presented in early pregnancy (<18 weeks) were included. Data for maternal thyroid-stimulating hormone, free thyroxine, thyroid peroxidase antibodies (at weeks 9–18 of pregnancy), and child IQ (assessed at a median of 6·0 years of age [95% range 5·6–7·9 years]) or brain MRI scans (done at a median of 8·0 years of age [6·2–10·0]) were obtained. Analyses were adjusted for potential confounders including concentrations of human chorionic gonadotropin and child thyroid-stimulating hormone and free thyroxine.\nFindings\nData for child IQ were available for 3839 mother–child pairs, and MRI scans were available from 646 children. Maternal free thyroxine concentrations showed an

inverted U-shaped association with child IQ (p=0·0044), child grey matter volume (p=0·0062), and cortex volume (p=0·0011). For both low and high maternal free thyroxine concentrations, this association corresponded to a 1·4–3·8 points reduction in mean child IQ. Maternal thyroid-stimulating hormone was not associated with child IQ or brain morphology. All associations remained similar after the exclusion of women with overt hypothyroidism and overt hyperthyroidism, and after adjustment for concentrations of human chorionic gonadotropin, child thyroid-stimulating hormone and free thyroxine or thyroid peroxidase antibodies (continuous or positivity).\nInterpretation\nBoth low and high maternal free thyroxine concentrations during pregnancy were associated with lower child IQ and lower grey matter and cortex volume. The association between high maternal free thyroxine and low child IQ suggests that levothyroxine therapy during pregnancy, which is often initiated in women with subclinical hypothyroidism during pregnancy, might carry the potential risk of adverse child neurodevelopment outcomes when the aim of treatment is to achieve high-normal thyroid function test results.\nFunding\nThe Netherlands Organisation for Health Research and Development (ZonMw) and the European Community's Seventh Framework Programme.","DOI":"10.1016/S2213-8587(15)00327-7","ISSN":"2213-8587","shortTitle":"Association of maternal thyroid function during early pregnancy with offspring IQ and brain morphology in childhood","journalAbbreviation":"The Lancet Diabetes & Endocrinology","author":[{"family":"Korevaar","given":"Tim I M"},{"family":"Muetzel","given":"Ryan"},{"family":"Medici","given":"Marco"},{"family":"Chaker","given":"Layal"},{"family":"Jaddoe","given":"Vincent W

V"},{"family":"Rijke","given":"Yolanda B","non-dropping-particle":"de"},{"family":"Steegers","given":"Eric A P"},{"family":"Visser","given":"Theo J"},{"family":"White","given":"Tonya"},{"family":"Tiemeier","given":"Henning"},{"family":"Peeters","given":"Robin P"}],"issued":{"date-parts":[["2016",1]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] study data. Ultimately, the changes in IQ are estimated for each impacted iodine intake group, and all of the impacted iodine intake groups' IQ decrements are averaged together based on the proportion of individuals in each iodine intake category. Table XII-4 shows the specific iodine intake groups and the proportion of non-pregnant women of childbearing age that fall into each group.

Table XII-4: Proportion of Population based on Maternal Iodine Intake Status

Iodine Intake Range (µg/ day) used for Benefits Analysis	Proportion of the population
0 to <55	7.14%
55 to <60	2.15%
60 to <65	1.06%
65 to < 70	1.86%
70 to <75	1.31%
75 to <80	3.10%
80 to <85	2.62%
85 to <90	1.20%
90 to <95	1.83%
95 to <100	2.94%
100 to <125	13.56%
125 to <150	9.08%
150 to <170	10.31%
170 to <300	24.47%
≥300	17.36%

Source: U.S. EPA (2019a).

These changes in child IQ are then monetized using the EPA's estimate of the value of an IQ point. This estimate reflects the discounted present value of lifetime income reductions attributable to a 1-point reduction in IQ at birth. Therefore, the present value depends on the discount rate. At a 3 percent discount rate, the estimate is $18,686 per IQ point; at a 7 percent discount rate the estimate is $3,631.

Other potential benefits not quantified or monetized include additional avoided health effects which cannot currently be monetized, improved public perception of water quality, as well as a possible reduction of other co-occurring contaminants that target the thyroid, such as nitrate, as a result of water treatment for removal of perchlorate. For example, all of the treatment technologies evaluated for this rule (ion exchange, biological treatment, and reverse osmosis) can also remove co-occurring nitrate from drinking water. Section XIII provides additional discussion of uncertainties in this analysis.

D. Comparison of Costs and Benefits

This section provides the estimates of costs and benefits that the EPA derived using the methods described above. It includes estimates for the proposed and alternative MCLs.

For the proposed MCL of 56 μg/L, Table XII-5 summarizes the total estimated cost of the proposed rule to water systems and primacy agencies, and Table XII-6 summarizes the estimated per-household cost for the system incurring treatment costs[16]. Table XII-7 summarizes

[16] For all households served by all of the systems subject to the monitoring costs as well as MCL compliance, the average annual cost is less than $0.20.

the estimated benefits. In both instances, the estimates based on the UCMR 1 sample are also national estimates because treatment costs occur only at large systems; there are no small system treatment costs or related benefits to extrapolate.

Table XII-5: Summary of Total Annualized Costs at MCL of 56 µg/L (Millions; 2017$)

Cost Component	3% Discount	7% Discount
Drinking Water Systems Treatment Costs	$0.65	$0.70
Drinking Water Systems Monitoring and Administration Costs[1]	$5.93	$6.38
Drinking Water Systems Costs Subtotal	$6.58	$7.07
State Administration Costs	$3.09	$3.20
Total Costs	$9.67	$10.28

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"00m0B8b8","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].
Detail may not sum to total because of independent rounding.
1. Costs include monitoring for all CWS and NTNCWS. Some consecutive systems that purchase 100% of their water from wholesale systems may not be required to monitor for perchlorate provided States allow integrated system agreements to include perchlorate among the monitoring requirements that the wholesale system fulfills for the consecutive system. The potential number of consecutive systems excluded from perchlorate monitoring depends on system and State decisions and, therefore, is unknown. Excluding monitoring costs for approximately 8,400 consecutive systems that do not report a water source facility (e.g., well or intake) in SDWIS/FED from the monitoring cost analysis reduces annualized monitoring costs by $0.8 million.

Table XII-6: Summary of Household-Level Annual Costs for Systems Treating to Comply with MCL at 56 µg/L (2017$)

Cost Range	3% Discount	7% Discount
Minimum	$11	$14
Average	$40	$47
Maximum	$69	$80

Source: [ADDIN ZOTERO_ITEM CSL_CITATION
{"citationID":"xTqTuaNv","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Table XII-7: Summary of Total Annualized Benefits of Avoided Lost IQ Decrements at MCL of 56 µg/L (Millions; 2017$)

Korevaar β distribution	Annual Delta IQ	3% Discount	7% Discount
Upper	243	$3.57	$0.60
Central	136	$2.00	$0.34
Lower	30	$0.44	$0.07

Source: [ADDIN ZOTERO_ITEM CSL_CITATION
{"citationID":"T7LDdiyn","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

For the alternative MCL of 18 µg/L, Table XII-8 summarizes the total cost of the proposed rule to water systems and primacy agencies, and Table XII-9 summarizes the per-household cost for systems requiring treatment, which vary across the systems. Table XII-10 summarizes the quantified benefits. At this threshold, one entry point for one small system in the

UCMR 1 data had an exceedance. Therefore, the EPA extrapolated the treatment costs and benefits from the UCMR 1 estimates to national estimates based on sampling weights.

Table XII-8: Summary of Total Annualized Costs at MCL of 18 μg/L (Millions; 2017$)

Cost Component	3% Discount (UCMR 1)[1]	7% Discount (UCMR 1)[1]	3% Discount (National)[1]	7% Discount (National)[1]
Drinking Water Systems Treatment Costs	$6.92	$7.29	$7.92	$8.37
Drinking Water Systems Monitoring and Administration Costs	$5.94	$6.38	$5.94	$6.38
Drinking Water Systems Costs Subtotal	$12.85	$13.67	$13.86	$14.75
State Administration Costs	$3.09	$3.21	$3.09	$3.21
Total Costs	$15.95	$16.88	$16.95	$17.96

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"H6Rcd4Hf","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Detail may not sum to total because of independent rounding.

1. The EPA applied statistical sampling weights to the results to extrapolate small system results to national results. The entry point at which a measurement exceeds 18 μg/L is one of 20 in its sample stratum; no other sample in the stratum had a measurement of perchlorate greater than the minimum reporting level. The entry point population of 2,155 represents 5.31% of the total population served by the six UCMR 1 systems in the stratum (40,574). Currently, the stratum population of 775,000 accounts for 1.32% of the 58.7 million national population served by small systems. Thus, the UCMR 1 results indicate that 0.07% (5.31% x 1.32%) of small system customers (approximately 41,100) may be exposed to perchlorate greater than 18 μg/L. The EPA calculated per-capita costs for the system and extrapolated to national level based on this population estimate.

2. Costs include monitoring for all CWS and NTNCWS. Under 40 CFR 141.29 some consecutive systems that purchase 100% of their water from wholesale systems may not be required to monitor for perchlorate provided primacy agencies, with EPA concurrence, allow integrated system agreements to include perchlorate among the monitoring requirements that the wholesale system fulfills for the consecutive system. The potential number of consecutive systems excluded from perchlorate monitoring depends on system and primacy agency decisions and, therefore, is unknown. Excluding monitoring costs for approximately 8,400 consecutive systems that do not report a water source facility (e.g., well or intake) in SDWIS/FED from the monitoring cost analysis reduces annualized monitoring costs by $0.8 million.

Table XII-9: Summary of Household-Level Annual Costs for Systems Treating to Comply with the MCL at 18 µg/L (2017$)

Cost Range	3% Discount (UCMR 1)[1]	7% Discount (UCMR 1)[1]	3% Discount (National)[1]	7% Discount (National)[1]
Minimum	$18	$24	$18	$24
Average	$38	$46	$38	$46
Max	$72	$84	$72	$84

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"uu13kmuC","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

1. National cost estimates include extrapolation for one small system entry point to national estimates based on sampling weights. The per-household costs are the same for the sample and national extrapolations because the small system cost extrapolation occurs on a per-capita basis.

Table XII-10: Total and Annualized Benefits of Avoided Lost IQ Decrements at 18 µg/L (Millions; 2017$)

Korevaar β distribution	Annual Delta IQ		UCMR 1		National[1]	
	UCMR 1	National[1]	3% Discount	7% Discount	3% Discount	7% Discount
Upper	442	447	$6.50	$1.10	$6.56	$1.11
Central	248	251	$3.65	$0.62	$3.68	$0.62
Lower	54	55	$0.80	$0.13	$0.80	$0.14

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"EN9pibZj","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

1. The EPA applied statistical sampling weights to the results to extrapolate small system results to national results. The entry point at which a measurement exceeds 18 µg/L is one of 20 in its sample stratum; no other sample in the stratum had a measurement of perchlorate greater than the minimum reporting level. The entry point population of 2,155 represents 5.31% of the total population served by the six UCMR 1 systems in the stratum (40,574). Currently, the stratum population of 774,780 accounts for 1.32% of the 58.7 million national population served by small systems. Thus, the UCMR 1 results indicate that 0.07% (5.31% x 1.32%) of small system customers (approximately 41,100) may be exposed to perchlorate greater than 18 µg/L. The EPA assumed that this population would incur benefits equivalent to the sampled entry point's population.

For the alternative MCL of 90 µg/L, Table XII-11 summarizes the total cost of the proposed rule to water systems and primacy agencies, and Table XII-12 summarizes the per-household cost for systems requiring treatment, which vary across the systems. Table XII-13 summarizes the quantified benefits. At this threshold, no small systems in the UCMR 1 data had an exceedance. Therefore, treatment costs and benefits for the UCMR 1 data are the national estimates.

Table XII-11: Summary of Total Annualized Costs at MCL of 90 μg/L (Millions; 2017$)

Cost Component	3% Discount	7% Discount
Drinking Water Systems Treatment Costs	$0.49	$0.52
Drinking Water Systems Monitoring and Administration Costs[1]	$5.93	$6.37
Drinking Water Systems Costs Subtotal	$6.42	$6.89
State Administration Costs	$3.09	$3.20
Total Costs	$9.51	$10.10

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"00m0B8b8","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Detail may not sum to total because of independent rounding.

1. Costs include monitoring for all CWS and NTNCWS. Some consecutive systems that purchase 100% of their water from wholesale systems may not be required to monitor for perchlorate provided States allow integrated system agreements to include perchlorate among the monitoring requirements that the wholesale system fulfills for the consecutive system. The potential number of consecutive systems excluded from perchlorate monitoring depends on system and State decisions and, therefore, is unknown. Excluding monitoring costs for approximately 8,400 consecutive systems that do not report a water source facility (e.g., well or intake) in SDWIS/FED from the monitoring cost analysis reduces annualized monitoring costs by $0.8 million.

Table XII-12: Summary of Household-Level Annual Costs for Systems Treating to Comply with MCL at 90 μg/L (2017$)

Cost Range	3% Discount	7% Discount
Minimum	$65	$76
Average	$65	$76
Maximum	$65	$76

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"xTqTuaNv","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. There is no variation in costs because treatment costs occur at one entry point. The household costs are slight lower compared to the maximum cost at 56 μg/L because treatment costs to meet an MCL of 90 μg/L are lower than the costs to meet an MCL of 56 μg/L.

Table XII-13: Summary of Total Annualized Benefits of Avoided Lost IQ Decrements at MCL of 90 μg/L (Millions; 2017$)

Korevaar β distribution	Annual Delta IQ	3% Discount	7% Discount
Upper	222	$3.26	$0.55
Central	124	$1.83	$0.31
Lower	27	$0.40	$0.07

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"T7LDdiyn","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

Table XII-14 provides a comparison of benefits and costs for three MCL values. First, the table shows the total annual costs and total annual benefits for each MCL. In all cases, the total costs are substantially higher than the potential range of quantifiable benefits. The table also shows the incremental impact on costs and benefits between an MCL of 56 μg/L and an MCL of 18 μg/L and between an MCL of 90 μg/L and 56 μg/L.

Section 1412(b)(4)(C) of the SDWA requires that when proposing a national primary drinking water regulation, "the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs." The infrequent occurrence of perchlorate at levels of health concern imposes high monitoring and administrative cost burdens on public water systems and the States. Based on a comparison of costs and benefits estimated at the proposed MCL of 56 µg/L using the best available science and data, the EPA Administrator has determined based upon the available information that the benefits of establishing an NPDWR for perchlorate do not justify the associated costs.

Under these circumstances, Section 1412(b)(6)(A) of the SDWA provides, with exceptions not relevant here, that "the Administrator *may*, after notice and opportunity for public comment promulgate a maximum contaminant level for the contaminant that maximizes health risk reduction benefits at a cost that is justified by the benefits." The EPA has evaluated the benefits and costs of alternative MCL values of 18 µg/L and 90 µg/L. However, based upon the available information the Administrator also finds that the benefits of an NPDWR at the alternative MCL values would not justify the resulting rule costs. The alternative MCLs would not increase net benefits, while compliance costs associated mainly with nationwide CWS monitoring requirements would remain relatively similar. Consistent with the discretion afforded the Agency by SDWA Section 1412(b)(6)(A) to decide whether or not to adjust an MCL to a level where the benefits justify the costs, the EPA is however proposing, and may finalize, the MCL of 56 µg/L notwithstanding the Agency's determination that benefits would not justify the costs.

Table XII-14: Comparison of Annual Costs and Benefits by MCL (Millions; 2017$)

MCL Value	Cost 3% Discount	Benefit 3% Discount	Cost 7% Discount	Benefit 7% Discount
UCMR 1				
90 µg/L	$9.51	$0.40 - $3.26	$10.10	$0.07 - $0.55

56 µg/L	$9.67	$0.44 - $3.57	$10.28	$0.07 - $0.60
18 µg/L	$15.95	$0.80 - $6.50	$16.88	$0.13 - $1.10
Incremental (from 90 µg/L to 56 µg/L)	$0.16	$0.04 - $0.31	$0.18	$0.0 – 0.05
Incremental (from 56 µg/L to 18 µg/L)	$6.28	$0.36 - $2.93	$6.60	$0.06 - $0.50
National				
90 µg/L	$9.51	$0.40 - $3.26	$10.10	$0.07 - $0.55
56 µg/L[1]	$9.67	$0.44 - $3.57	$10.28	$0.07 - $0.60
18 µg/L	$16.95	$0.80 - $6.56	$17.96	$0.14 - $1.11
Incremental (from 90 µg/L to 56 µg/L)	$0.16	$0.04 - $0.31	$0.18	$0.0 – 0.05
Incremental (from 56 µg/L to 18 µg/L)	$7.28	$0.36 - $2.99	$7.69	$0.07 - $0.51

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"E0mmmXDK","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Detail may not sum to total because of independent rounding.

1. For the proposed MCL of 56 µg/L and the alternative MCL of 90 µg/L, the national estimates are the same as the estimates based on UCMR 1 data because there were no small system sample results to extrapolate to national small system estimates. At an MCL of 18 µg/L, national estimates include extrapolation for one small system entry point to national estimates based on sampling weights described above.

XIII. Uncertainty Analysis

The EPA has presented an extensive discussion of the uncertainties in the key analyses informing this proposal in the uncertainty section of the MCLG Approaches Report and the uncertainties section of the Economic Analysis document (*USEPA, 2018b; USEPA, 2019a).* A summarized description of these uncertainties are presented below.

A. Uncertainty in the MCLG Derivation

Each input into the analysis to inform the MCLG is a decision point associated with uncertainty. There is uncertainty in different aspects of the BBDR model, ranging from structural and functional relationships to specific parameter values for early pregnancy. There are very few data available to calibrate the pharmacokinetic aspects of the model, particularly at the life stage of interest. Also, the BBDR model does not explicitly consider the effect of the presence of other goitrogens (e.g. thiocyanate, nitrate) or effects of thyroid disease states. Toxicodynamic aspects such as competitive inhibition at the NIS, depletion of iodide stores under different iodine intake levels and physiological states, and the ability of the TSH feedback loop to compensate for perturbations in thyroid function each have their own uncertain features. Additional uncertainty is introduced by linking the BBDR model estimates of maternal fT4 to altered neurodevelopment in offspring. None of the studies used to evaluate potential adverse neurodevelopmental outcomes in offspring born to hypothyroxinemic mothers was performed in the U.S. None of the studies measured perchlorate exposure. Not all the studies measured iodide levels in the study populations. The state of the science on the relationship between maternal fT4 levels and offspring neurodevelopment is constantly evolving. There are numerous indices used to assess neurodevelopmental impacts and there is some uncertainty regarding the selection of IQ as the critical endpoint for setting the MCLG.

A recently published paper evaluating the EPA's BBDR model and MCLG Approaches, reiterated the uncertainties the Agency identified in its analyses and questions the use of these quantitative tools for perchlorate in a regulatory context (Clewell et al., 2019).

B. Uncertainty in the Economic Analysis

The EPA provides discussions regarding several sources of uncertainty in the benefit and cost estimates in the Health Risk Reduction and Cost Analysis (USEPA, 2019a). Table XIII-1 provides a summary of sources of uncertainty and their potential effects on estimated costs and benefits. The following discussion addresses uncertainties specific to the benefits analysis.

Table XIII-1. Sources of Uncertainty in Economic Analysis

Description	Potential effect
Baseline Occurrence	
UCMR 1 data are more than one decade old; actual occurrence could be lower (e.g., because of contaminant cleanup) or higher (e.g., because new systems use perchlorate-contaminated source water).	± (benefits and costs will change in the same direction)
UCMR 1 data include a sample of small systems; the Stage 1 results (entry point maximums) indicate that no small systems would exceed 56 μg/L or 90 μg/L and that one small system would exceed 18 μg/L; it is possible that there are additional small systems where the baseline perchlorate is greater than the MCLs that are not captured in the national extrapolation results.	− (benefits and costs will change in the same direction)
The EPA assumed a uniform distribution of system population served across the entry points; the actual entry point service population could be greater than or less than the estimates.	± (benefits and costs will change in the same direction)
Benefits Analysis	
The health risks and risk reductions are based on maximum recorded concentration estimates and thus do not account for exposures to concentrations greater than or less than this recorded maximum.	± (benefits only)
The EPA assumed that baseline fT4 is equal to the median, which likely underestimates disease benefits as the logarithmic relationship between maternal fT4 and child IQ leads to larger relative changes in fT4, with increasing levels of perchlorate and lower levels of baseline fT4.	− (benefits only)
The EPA assumed a median TSH feedback loop strength for the exposed population does not incorporate the variability in the feedback mechanism of the body's creation of TSH in response to decreasing fT4.	± (benefits only)

Description	Potential effect
The EPA used a 90th percentile water intake rate to derive the MCLG and the dose-response equations for the benefits analysis. This approach results in a protective MCLG value, but may overstate intake for the benefits analysis.	+ (benefits only)
The IQ valuation uses estimates that the EPA derived using the same approach as Salkever (1995). Results from other IQ valuation studies might result in higher or lower benefit estimates.	± (benefits only)
The benefits analysis is based on a single health endpoint and the value of the endpoint is based solely on lost earnings.	− (benefits only)
Cost Analysis	
The EPA assumed that systems requiring treatment would incorporate a safety factor – treating to 80% of the proposed MCL or alternative MCL, which increases costs and benefits.	+ (benefits and costs will change in the same direction)
The EPA assumed that all entry points requiring treatment would implement ion exchange, which may overestimate costs if non-treatment is an option for one or more entry points or underestimate costs if site-specific conditions result in higher costs at one or more entry points.	± (costs only)
The EPA developed a monitoring schedule that assumed a uniform distribution of initial monitoring costs over three years; actual costs will vary.	± (costs only)
The EPA assumed that long-term monitoring costs would occur in the last year of the applicable three-year monitoring period or nine-year monitoring cycle; systems may conduct monitoring in an earlier year of the period or cycle.	− (costs only)
The EPA assumed that 90% of ground water systems and 40% of surface water systems obtain perchlorate monitoring waivers; the actual percentages may vary.	± (costs only)

1. A "−" symbol indicates that benefits and/or costs will tend to be underestimated. A "+" symbol indicates that benefits and/or costs will tend to be overestimated. A "±" symbol indicates an unknown direction of uncertainty, i.e., benefits and/or costs could be underestimated or overestimated.

The EPA acknowledges the uncertainty regarding the quantitative health risk reduction. In particular, the Agency assumed it could estimate risk reductions based on evidence of a quantifiable relationship between thyroid hormone changes and neurodevelopmental outcomes.

There are a number of potential benefits of reducing perchlorate in drinking water that were not quantified as part of this analysis, which may result in an underestimate of actual benefits. As described by the SAB "children exposed gestationally to maternal hypothyroxinemia (without hypothyroidism) show reduced levels of global and specific cognitive abilities, as well as increased rates of behavior problems including greater dysregulation in early infancy and attentional disorders in childhood (Man et al., 1991; Pop et al., 1999; Pop et al., 2003; Kooistra et al., 2006)" (p. 10, SAB for the U.S. EPA, 2013). The EPA's literature review identified potential relationships between maternal thyroid hormone alterations and the risk of schizophrenia, ADHD, expressive language delay, reduced school performance and increased odds of autism, among others, none of which are being currently quantified in this assessment. Other potentially omitted benefits include risks associated with effects of thyroid disorders in adults, including cardiovascular disease risk; changes in thyroid hormone levels and their relationship with total cholesterol, LDL cholesterol, and triglycerides; as well as a possible relationship between increases in TSH and risk of fatal coronary heart disease. Treating for perchlorate in drinking water could also potentially remove nitrate, which is a co-occurring contaminant and a goitrogen. These additional potential health endpoints are not monetized in this benefits analysis. The assumptions used to account for the previously mentioned variability of the BBDR model inputs and uncertainty surrounding the relationship between maternal fT4 and child IQ discussed above may result in an overestimate of the monetized benefits. Because IQ is a surrogate for broad range of potential neurodevelopmental risks, it is unclear whether the analysis as a whole over- or under-estimates the monetized benefits of a reduction of perchlorate in drinking water.

XIV. Request for Comment on Proposed Rule

While all comments relevant to the national primary drinking water regulation for perchlorate proposed today will be considered by the EPA, comments on the following issues will be especially helpful to the EPA in developing a final rule. The EPA specifically requests comment on the following topics.

- The adequacy and uncertainties of the BBDR model developed by the EPA to predict thyroid hormone level changes caused by perchlorate exposure to pregnant women with low iodide intake, including the model and model parameters and assumptions (Section III and Approaches Report).
- The adequacy and uncertainties of the EPA's review and application of the epidemiologic literature to quantify the relationship between thyroid hormone changes in pregnant women and neurodevelopmental effects including the assumptions, the selection of the approach used, and the study used (Section III and Approaches Report).
- The adequacy and uncertainties of the methodology to derive the MCLG including points of departure, assumptions, uncertainty factor, and relative source contribution (Section III and Technical Support Document: Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water).
- The proposed MCLG and MCL of 56 μg/L as well as the alternative MCLG and MCL values of 18 μg/L and of 90 μg/L.

- The feasibility of the proposed MCL of 56 µg/L as well as the feasibility of the alternative MCLs of 18 µg/L and 90 µg/L.
- The adequacy of the underlying assumptions and analysis of occurrence (Section VI).
- The costs and availability of Treatment Technologies (Section X).
- The adequacy of the underlying estimates, assumptions and analysis used to estimate costs and describe unquantified costs including the estimates of monitoring frequency, likelihood of systems receiving a monitoring waiver, the administrative labor rate and the operator labor rate. (Section XII and the Health Risk Reduction Cost Analysis).
- The adequacy of the underlying estimates, assumptions and analysis used to estimate benefits and describe unquantified benefits (Section XII and the Health Risk Reduction Cost Analysis).
- Potential implementation challenges associated with the proposed perchlorate regulation that the EPA should consider, specifically for small systems.
- The Administrator's finding in accordance with Section 1412(b)(4)(C) of the SDWA that the benefits of the proposed 56 µg/L MCL for perchlorate do not justify the costs, and the information that supports that determination as described in Section XII of this notice.
- The Administrator's proposal to, consistent with the discretion afforded him by SDWA Section 1412(b)(6)(A), adopt an MCL of 56 µg/L notwithstanding the Agency's SDWA Section 1412(b)(4)(C) determination that the benefits of the MCL would not justify its costs.

- The Agency's conclusion that no alternative MCL, including the alternative MCL values of 18 μg/L and 90 μg/L discussed above, would "maximize health risk reduction benefits at a cost that is justified by the benefits" and the information and analytical approaches used to arrive at that conclusion. The EPA is especially interested in comments suggesting other approaches to deriving an MCL for which the benefits justify the costs.

XV. Request for Comment on Potential Regulatory Determination Withdrawal

The EPA is soliciting comments on withdrawing the 2011 Regulatory Determination (see Section II-C, Regulatory History) based on several factors. First, the findings, described in the occurrence section (section VI) and in the updated health effects assessment (Section III), suggest that perchlorate does not occur in public water systems with a frequency and at levels of public health concern[17] and suggest that the regulation of perchlorate does not present a meaningful opportunity for health risk reduction for persons served by public water systems. The proposed regulation would require over sixty thousand public water systems to monitor for perchlorate, but the available data indicates that very few would find it at levels of public health concern. Specifically, perchlorate occurrence information suggests that at an MCL of 56 μg/L only 2 systems (0.004% of all water systems in the U.S.) would exceed the regulatory threshold. Even at an MCL of 18 μg/L, there would only be 15 systems (0.03% of all water systems in the

[17] As shown in Section VI of this notice there is infrequent occurrence of perchlorate at either 56 μg/L, 18 μg/L or 90 μg/L, which are the possible levels expected to cause adverse human health effects.

U.S.) that would exceed the regulatory threshold. Only one system would exceed the alternative MCL of 90 μg/L.

The EPA notes that in 2008, the EPA stated in its preliminary regulatory determination that perchlorate did not occur with a frequency and at levels of public health concern in public water systems based upon the health effects and occurrence information available at that time, which indicated that 0.8% of public water system had perchlorate at levels exceeding the HRL of 15 μg/L. The EPA also stated that there was not a meaningful opportunity for a NPDWR to reduce health risks based upon the estimates at that time that 0.9 million people had perchlorate levels above the HRL.

The EPA further notes that the Agency has previously determined CCL1 and CCL2 contaminants did not occur with frequency at levels of public health concern when the percentage of water systems exceeding the HRL were greater than the frequency of perchlorate occurrence level at the proposed MCL (0.004% of all water systems in the U.S.). For example, in 2003 the EPA determined that aldrin did not occur with a frequency and at levels of public health concern based upon data that showed 0.2% of water systems had aldrin at levels greater than the HRL. The EPA also concluded that there was not a meaningful opportunity for health risk reduction for persons served through a drinking water regulation based on this occurrence data and the estimate that these systems above the HRL served approximately 1 million people (USEPA, 2003). In 2008 the EPA determined that DCPA Mono- and Di-Acid degradates did not occur with a frequency and at levels of public health concern based on data that showed 0.~~13~~03%

of water systems exceeded the HRL. The EPA also included that there was not a meaningful opportunity for health risk reduction through a drinking water regulation based on this occurrence data and the estimate that these systems above the HRL served approximately 100,000 people (USEPA, 2008e).

SDWA Section 1412(b)(1)(A)(iii) states that the determination regarding the meaningful opportunity is "in the sole judgement of the Administrator" and therefore there may be other factors that contribute to this determination for any given contaminant.

If, after consideration of public comment, the EPA withdraws the perchlorate regulatory determination, there will be no NPDWR for perchlorate, although the EPA can re-list perchlorate on the CCL and proceed to regulation in the future if the occurrence or risk information changes. As with other unregulated contaminants, the EPA could address the limited instances of elevated levels of perchlorate by working with the states or using its SDWA Section 1431 imminent and substantial endangerment or Section 1412(b)(1)(f) health assessment authorities, as appropriate. The EPA also requests comments on what guidance it could provide the public if the regulatory determination for perchlorate is withdrawn.

XVI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action since it raises novel legal or policy issues. It was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

The EPA evaluated the potential costs to States and utilities and the potential benefits of the proposed rule. This analysis, *Health Risk Reduction Cost Analysis of the Proposed Perchlorate Rule (USEPA, 2019a)* is available in the docket and is summarized in section XI.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Cost

This action is expected to be an Executive Order 13771 regulatory action. Details on the estimated costs of this proposed rule can be found in the EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*. The information collection requirements are not enforceable until OMB approves them.

The monitoring information collected as a result of this rule will allow the States and the EPA to evaluate compliance with the rule. For the first 3-year period following rule promulgation, the major information requirements concern primacy agency activities to implement the rule including adopting the NPDWR into state regulations, providing training to state and PWS employees, updating their monitoring data systems, and reviewing system monitoring data and waiver requests. Compliance actions for drinking water systems (including monitoring, administration, and treatment costs) would not begin until after Year 3 due to the proposed effective date of this rule.

The estimate of annual average burden hours for the proposed rule during the first three years following promulgation is 48,539 hours. The annual average cost estimate is $7.4 million for labor. The burden hours per response is 2,648 hours and the cost per response is $134,159. The frequency of response (average responses per respondent) is 1 for primacy agencies, annually (for upfront administrative activities to implement the rule). The estimated number of likely respondents is 55 over the three-year period (for an average of 18.3 each year).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, to the EPA at the public docket established for this rule, which includes the ICR, Docket ID No. **EPA-HQ-OW-2018-0780**. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to OIRA_submission@omb.eop.gov, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than **[insert date 30 days after publication in the *Federal Register*]**. The EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The Agency has determined that the proposed MCL of 56 μg/L will not result in annual costs that exceed one percent of revenue for small systems affected by the proposed rule.

The small entities subject to the requirements of this action are public water systems serving 10,000 or fewer persons. This is the threshold specified by Congress in the 1996 Amendments to the Safe Drinking Water Act for small system flexibility provisions. In accordance with the RFA requirements, the EPA proposed using this alternative definition in the Federal Register, (63 FR 7620, February 13, 1998), requested public comment, consulted with the Small Business Administration (SBA), and expressed its intention to use the alternative definition for all future drinking water regulations in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). As stated in that final rule, the alternative definition is applied to this proposed regulation.

The proposed rule contains provisions that would affect 58,325 CWS and NTNCWS serving 10,000 or fewer people. In order to meet the proposed rule requirements, all of these systems will need to conduct perchlorate monitoring. At the proposed MCL of 56 µg/L, the UCMR 1 monitoring data indicate that no small systems would be required to incur costs to reduce the levels of perchlorate in drinking water, therefore, all small PWSs will incur monitoring costs only. Impacts on small entities are described in more detail in Chapter 7 of the Health Risk Reduction Cost Analysis of the Proposed Perchlorate Rule (USEPA, 2019a). Table XII-1 and Table XII-2 show the annual compliance costs of the proposed rule on the small entities by system size for public and private systems, respectively. Based on a comparison of annual costs with annual revenue estimates, the EPA has determined that no small systems will experience an impact of one percent or greater of average annual revenues (USEPA 2019a).

Table XII-1: Annualized Monitoring and Administrative Costs as a Percentage of Average Annual Revenue for Small Public CWSs by Size Category

Size Category	Average Annual Revenues[a]	3% Discount[b]	7% Discount[b]
Population served <100	$224,248	$88 (0.04%)	$94 (0.04%)
Population served 101-500	$197,315	$88 (0.04%)	$94 (0.05%)

Population served 501-3,300	$202,382	$88 (0.04%)	$94 (0.05%)
Population served 3,301-10,000	$1,092,187	$88 (0.01%)	$94 (0.01%)

Source: Perchlorate Benefit-Cost Analysis Spreadsheet available in the proposed rule docket (EPA-HQ-OW-2018-0780)

a. Based on the CWSS [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ZkgC4dzL","properties":{"formattedCitation":"(USEPA, 2009c Table 65)","plainCitation":"(USEPA, 2009c Table 65)","noteIndex":0},"citationItems":[{"id":924,"uris":["http://zotero.org/groups/945096/items/DZNAAV6M"],"uri":["http://zotero.org/groups/945096/items/DZNAAV6M"],"itemData":{"id":924,"type":"article","title":"2006 Community Water System Survey - Volume II: Detailed Tables and Survey Methodology","URL":"https://www.epa.gov/dwstandardsregulations/community-water-system-survey","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2009",5]]},"accessed":{"date-parts":[["2018",8,16]]}},"suffix":"Table 65"}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] and updated to 2017$ based on the chained consumer price index for fuels and utilities in U.S. city average, all urban consumers [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"rkwEpGYT","properties":{"formattedCitation":"(Bureau of Labor Statistics (BLS), 2018a)","plainCitation":"(Bureau of Labor Statistics (BLS), 2018a)","noteIndex":0},"citationItems":[{"id":984,"uris":["http://zotero.org/groups/945096/items/E3I7HRK8"],"uri":["http://zotero.org/groups/945096/items/E3I7HRK8"],"itemData":{"id":984,"type":"article","title":"Chained consumer price index for fuels and utilities in U.S. city average, all urban consumers, 2000 to 2018","author":[{"literal":"Bureau of Labor Statistics (BLS)"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Revenues include all sources of revenue including water revenue, non-water revenue, and municipal transfers to water systems.

b. Total annual monitoring and administrative costs for PWSs are approximately $6.6 million to $7.1 million annually (Exhibit 5 5), with $5.1 million to $5.5 million accruing to small PWSs. Based on 58,325 small systems, this yields an average annual per-system cost of $88 (3% discount rate) to $94 (7% discount rate).

Table XII-2: Annualized Monitoring and Administrative Costs as a Percentage of Average Annual Revenue for Small Private CWSs by Size Category

Size Category	Average Annual Revenues[a]	3% Discount[b]	7% Discount[b]
Population served <100	$139,911	$88 (0.06%)	$94 (0.07%)
Population served 101-500	$351,974	$88 (0.03%)	$94 (0.03%)
Population served 501-3,300	$254,706	$88 (0.03%)	$94 (0.03%)
Population served 3,301-10,000	$951,692	$88 (0.01%)	$94 (0.01%)

Source: Perchlorate Benefit-Cost Analysis Spreadsheet available in the proposed rule docket (EPA-HQ-OW-2018-0780)

a. Based on the CWSS [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ZkgC4dzL","properties":{"formattedCitation":"(USEPA, 2009c Table 65)","plainCitation":"(USEPA, 2009c Table 65)","noteIndex":0},"citationItems":[{"id":924,"uris":["http://zotero.org/groups/945096/items/DZNAAV6M"],"uri":["http://zotero.org/groups/945096/items/DZNAAV6M"],"itemData":{"id":924,"type":"article","title":"2006 Community Water System Survey - Volume II: Detailed Tables and Survey Methodology","URL":"https://www.epa.gov/dwstandardsregulations/community-water-system-survey","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2009",5]]},"accessed":{"date-parts":[["2018",8,16]]}},"suffix":"Table 65"}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] and updated to 2017$ based on the chained consumer price index for fuels and utilities in U.S. city average, all urban consumers [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"rkwEpGYT","properties":{"formattedCitation":"(Bureau of Labor Statistics (BLS), 2018a)","plainCitation":"(Bureau of Labor Statistics (BLS), 2018a)","noteIndex":0},"citationItems":[{"id":984,"uris":["http://zotero.org/groups/945096/items/E3I7HRK8"],"uri":["http://zotero.org/groups/945096/items/E3I7HRK8"],"itemData":{"id":984,"type":"article","title":"Chained consumer price index for fuels and utilities in U.S. city average, all urban consumers, 2000 to 2018","author":[{"literal":"Bureau of Labor Statistics (BLS)"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Revenues include all sources of revenue including water revenue and non-water revenue.
b. Total annual monitoring and administrative costs for PWSs are approximately $6.6 million to $7.1 million annually (Exhibit 5 5), with $5.1 million to $5.5 million accruing to small PWSs. Based on 58,325 small systems, this yields an average annual per-system cost of $88 (3% discount rate) to $94 (7% discount rate).

E. Unfunded Mandates Reform Act

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538. The action imposes minimal enforceable duty on any state, local or tribal governments or the private sector

Based on the cost estimates detailed in Section XI, the EPA determined that compliance costs in any given year would be below the threshold set in UMRA, with maximum single-year costs of approximately $10.2 million. The EPA has determined that this rule contains a federal mandate that would not result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects of greater than $25 million on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Annual costs are estimated to range from $9.6 million at a 3 percent discount rate to $10.2 million using a 7 percent, with $6.5 million to $7.0 million annually accruing to public entities. The EPA has concluded that this proposed rule may be of interest because it may impose direct compliance costs on State or local governments, and the federal government will not provide the funds necessary to pay those costs.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

The EPA has concluded that this proposed rule may have Tribal implications, because it may impose direct compliance costs on Tribal governments, and the federal government would not provide the funds necessary to pay those costs. The EPA has identified 768 water systems with 1,167 entry points under Native American ownership that may be subject to the proposed rule. They would bear an estimated total annualized cost of $74,100 at a 3 percent discount rate ($79,625 at 7 percent) to implement this rule as proposed, with all costs attributable to monitoring and administrative costs. Estimated average annualized cost per system ranges from $96 at a 3 percent discount rate to $104 at a 7 percent discount rate.

Accordingly, the EPA provides the following Tribal summary impact statement as required by section 5(b) of Executive Order 13175. The EPA consulted with representatives of

Tribal officials early in the process of developing this proposed regulation to permit them to have meaningful and timely input into its development. The EPA conducted consultation with Indian Tribes which included a webinar with interested tribes on February 28, 2012, to request input and provide rulemaking information to interested parties. A meeting summary report is available on the docket for public inspection (USEPA 2012a). The EPA notes that 751 of the 768 Tribal systems identified by the Agency as subject to the proposed rule are small systems that are expected to incur only monitoring costs. Due to the health risks associated with perchlorate, capital expenditures needed for compliance with the rule would be eligible for federal funding sources, specifically the Drinking Water State Revolving Fund. In the spirit of Executive Order 13175, and consistent with the EPA policy to promote communications between the EPA and Tribal governments, the EPA specifically solicits additional comment on this proposed rule from Tribal officials.

H. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866; however, the environmental health risk addressed by this action may have a disproportionate effect on children. Accordingly, the EPA evaluated the environmental health or safety effects of perchlorate on children. The results of this evaluation are contained in the Health Effects Technical Support Document (USEPA 2018a) and described in section III of this preamble. The EPA has evaluated the risk associated with perchlorate in drinking water for the sensitive subpopulation – offspring of pregnant women exposed to perchlorate during the first trimester – and established a proposed MCLG that is protective of this subpopulation as well as other children. The EPA also estimated the health risk reduction of the proposed and alternative MCLs. This analysis is described in the Health Risk Reduction and Cost Analysis for the proposed rule (USEPA 2019a) and is summarized in section XI of this preamble. Copies of the Health Effects Technical Support Document and Economic Analysis and supporting information are available in the public docket for today's proposal.

I. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This determination is based on the following analysis.

The first consideration is whether the proposed rule would adversely affect the supply of energy. The proposed rule does not regulate power generation, either directly or indirectly. The public and private water systems that the proposed rule regulates do not generate power. Further, the cost increases borne by customers of water utilities as a result of the proposed rule are a low percentage of the total cost of water, except for a few water systems that might install treatment technologies and would likely spread that cost over their customer base. In sum, the proposed rule does not regulate the supply of energy, does not generally regulate the utilities that supply energy, and is unlikely to affect significantly the customer base of energy suppliers. Thus, the proposed rule would not translate into adverse effects on the supply of energy.

The second consideration is whether the proposed rule would adversely affect the distribution of energy. The proposed rule does not regulate any aspect of energy distribution. The water systems that are regulated by the proposed rule already have electrical service. At the proposed MCL, one entry point at one system may require incremental power to operate new treatment processes. The increase in peak electricity demand at water utilities is negligible. Therefore, the EPA estimates that the existing connections are adequate and that the proposed rule has no discernable adverse effect on energy distribution.

The third consideration is whether the proposed rule would adversely affect the use of energy. Because only one system is expected to add treatment technologies that use electrical power, this potential impact on sector demand or overall national demand for power is negligible.

Based on its analysis of these considerations, the EPA has concluded that proposed rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

J. National Technology Transfer and Advancement Act of 1995

The proposed rule could involve voluntary consensus standards in that it would require monitoring for Perchlorate. The EPA proposed five analytical methods for the identification and quantification of perchlorate in drinking water. The EPA methods 314.0, 314.1, 314.2, 331.0, and 332.0 incorporate quality control criteria which allow accurate quantitation of perchlorate. Additional information about the analytical methods is available in section VII of this notice.

The EPA's monitoring and sampling protocols generally include voluntary consensus standards developed by agencies such as ASTM International, Standard Methods and other such bodies wherever the EPA deems these methodologies appropriate for compliance monitoring. The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA has determined that this proposed rule would not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it would increase the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

The public is invited to comment on this aspect of the proposed rulemaking and, specifically, to recommend additional methods to address Environmental Justice concerns from establishing a drinking water rule for perchlorate in drinking water.

XVII. Consultations with the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with sections 1412(d) and 1412(e) of the Safe Drinking Water Act (SDWA), the Agency consulted with the National Drinking Water Advisory Council (NDWAC or the Council); the Secretary of Health and Human Services; and with the EPA Science Advisory Board. The Agency consulted with NDWAC during the Council's October 4-5, 2012 meeting. A summary of the NDWAC recommendations is available in the National Drinking Water Advisory Council, Fall 2012 Meeting Summary Report (NDWAC, 2012b) and the docket for this proposed rule. The EPA carefully considered NDWAC recommendations during the development of a proposed drinking water rule for perchlorate.

On May 29, 2012, the EPA sought guidance from the EPA Science Advisory Board (SAB) on how best to consider and interpret life stage information, epidemiological and biomonitoring data since the publication of the National Research Council 2005 report, the Agency's physiologically-based pharmacokinetic (PBPK) analyses, and the totality of perchlorate health information to derive a Maximum Contaminant Level Goal (MCLG) for perchlorate (USEPA, 2012; NRC, 2005). On May 29, 2013, the EPA received significant input from SAB, summarized in the report, SAB Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate (USEPA, 2013a).

On July 15, 2013, the EPA responded by stating that the Agency would consider all the recommendations from the SAB, as it continued working on the development of the rulemaking process for perchlorate (USEPA 2013b). To address SAB recommendations, the EPA collaborated with Food and Drug Administration (FDA) scientists to develop PBPK/pharmacodynamic (PD), or biologically based dose-response (BBDR), models that incorporate all available health related information on perchlorate to predict changes in thyroid hormones in sensitive life stages exposed to different dietary iodide and perchlorate levels (USEPA 2017). As recommended by SAB, the EPA developed these models based upon perchlorate's mode of action (i.e., iodide uptake inhibition by the thyroid) (USEPA 2013a). Additional details are in section III.C. of this notice and in the Health Effects of Perchlorate support document located in the docket for this proposed rule.

In accordance with SAB recommendations, the EPA developed a two-stage approach to integrate BBDR model results with data on neurodevelopmental outcomes from epidemiological studies, this approach allowed the Agency to link maternal thyroid hormones levels as a result of low iodine intake and perchlorate exposure, to derive an MCLG that directly addresses the most sensitive life stage (USEPA 2013a).

On March 25, 2019, the EPA consulted with the Department of Health and Human Services (HHS). The EPA provided information to HHS officials on the draft proposed perchlorate regulation and considered HHS input as part of the interagency review described in section XVII.A.

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List of Subjects in 40 CFR Parts 141, and 142

Administrative practice and procedure, Chemicals, Indians-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated:___________________

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Andrew R. Wheeler,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency proposes to amend 40 CFR part 141 and 40 CFR part 142 as follows:

PART 141 - NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for part 141 continues to read as follows:

   Authority: 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9, and 300j-11.

2. Amend § 141.6 by revising paragraph (a) and adding paragraph (l).

3. Amend § 141.23 by:

   a. Revising the title in the table in paragraph (a)(4)(i);

   b. Adding "Perchlorate" in alphabetical order, in the table in paragraph (a)(4)(i);

   c. Adding "perchlorate" in paragraph (a)(5);

   d. Adding "perchlorate" in alphabetical order, in paragraph (c);

   e. Adding paragraph (c)(10);

   f. Adding "perchlorate" in alphabetical order, in paragraph (f)(1);

   g. Adding "perchlorate" in alphabetical order, to the first sentence in paragraph (i)(1);

   h. Adding "perchlorate" in alphabetical order, to the first sentence in paragraph (i)(2);

   i. Revising paragraph (i)(3);

   j. Revising paragraph (k)(1);

k. Adding "perchlorate" in alphabetical order, to the second sentence in paragraph (k)(1);

l. Adding an entry for "21. Perchlorate" in alphabetical order, in the table in paragraph (k)(1);

m. Adding "perchlorate" in alphabetical order, to paragraph (k)(2);

n. Adding "Perchlorate" in alphabetical order, in the table in paragraph (k)(2);

o. Adding "perchlorate" in alphabetical order, to the third sentence in paragraph (k)(3); and

p. Adding an entry for "Perchlorate" in alphabetical order, in the table in paragraph (k)(3)(ii).

4. Amend § 141.51 by adding an entry for "Perchlorate" in alphabetical order, in the table in paragraph (b).

5. Amend § 141.60 by adding paragraph (b)(5).

6. Amend § 141.62 by:

a. Adding an entry (17) for "Perchlorate" in paragraph (b);

b. Adding an entry for "Perchlorate" in alphabetical order, to the table in paragraph (c);

c. Adding an entry "14 = Biological Treatment" in the table Key to BATs in paragraph (c);

d. Adding paragraph (e); and

e. Adding a table in paragraph (e).

7. Amend Appendix A to Subpart O of Part 141 by adding an entry for "Perchlorate" in the table entitled "APPENDIX A TO SUBPART O OF PART 141 – REGULATED CONTAMINANTS."
8. Amend Appendix A to Subpart Q of Part 141 by adding an entry for "Perchlorate" in the table entitled "APPENDIX A TO SUBPART Q OF PART 141 - NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTIFICATION."
9. Amend Appendix B to Subpart Q of Part 141 by adding an entry for "Perchlorate" in the table entitled "APPENDIX B TO SUBPART Q OF PART 141 – STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION."

The revisions and additions read as follows:

Subpart A—General

*****

§ 141.6 Effective Dates.

(a) Except as provided in paragraphs (b) through (l) of this section the regulations set forth in this part shall take effect on June 24, 1977.

*****

(l) The regulations contained in the revisions to §§141.23(a)(4)(i), 141.23(a)(5), 141.23(c),141.23(f)(1), 141.23(i)(1)-(2), 141.23(k)(1)-(3), 141.23(k)(3)(ii), 141.51(b), 141.60(b)(5), 141.62(b), 141.62(c), 141.62(e), Appendix A to Subpart O and Appendix A and B to Subpart Q are effective for the purposes of compliance on [insert date].

Subpart C—Monitoring and Analytical Requirements

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§141.23 Inorganic chemical sampling and analytical requirements.

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(a)***

(4)***

(i)***

DETECTION LIMITS FOR INORGANIC CONTAMINANTS (COMPOSITED SAMPLES)

Contaminant	MCL (mg/l)	Methodology	Detection limit (mg/l)
*******	*******	*******	*******

Perchlorate	0.056	Ion Chromatography	0.00053
		Inline Column Concentration/Matrix Elimination Ion Chromatography with Suppressed Conductivity Detection	0.00003
		Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection	0.000012-0.000018
		Liquid Chromatography Electrospray Ionization Mass Spectrometry	0.000005 (Tandem Mass Spectrometry [MS/MS]) 0.000008 (Selected Ion Monitoring [SIM])
		Ion Chromatography with Suppressed Conductivity and Electrospray Ionization Mass Spectrometry	0.00002
*******	*******	*******	*******

*****

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(c)***

(10) Community water systems and non-transient non-community water systems must conduct initial monitoring for perchlorate as follows:

(i) Community water systems serving greater than 10,000 persons without acceptable historic data, as defined below, must collect four consecutive quarterly samples at all sampling points between January 1, 2023, and December 31, 2025.

(ii) Community water systems serving 10,000 or fewer persons and non-transient non-community water systems without acceptable historic data, as defined below, must collect four consecutive quarterly samples at all sampling points between January 1, 2026, and December 31, 2028.

(iii) Grandfathering of data: States may allow historical monitoring data collected at a sampling point to satisfy the initial monitoring requirements for that sampling point, for the following situations.

(A) To satisfy initial monitoring requirements, community water systems serving greater than 10,000 persons having only one entry point to the distribution system may use the monitoring data from the compliance monitoring period between January 1, 2020, and December 31, 2022. Community water systems serving 10,000 or fewer persons and non-transient non-community water systems having only one entry point to the distribution system may use the monitoring data from the compliance monitoring period between January 1, 2023, and December 31, 2025.

(B) To satisfy initial monitoring requirements, a system with multiple entry points and having appropriate historical monitoring data for each entry point to the distribution system may use the monitoring data from the compliance monitoring period that began between January 1, 2020, and December 31, 2022, for community water systems serving greater than 10,000 persons and between January 1, 2023, and December 31, 2025, for community water systems serving 10,000 or fewer persons and for non-transient non-community water systems.

(C) To satisfy initial monitoring requirements, a system with appropriate historical data for a representative point in the distribution system may use the monitoring data from the compliance monitoring period between January 1, 2020, and December 31, 2022, for community water systems serving greater than 10,000 persons and between January 1, 2023, and December 31, 2025, for community water systems serving 10,000 or fewer persons and for non-transient non-community water systems, provided that the State finds that the historical data satisfactorily demonstrate that each entry point to the distribution system is expected to be in compliance based upon the historical data and reasonable assumptions about the variability of contaminant levels between entry points. The State must make a written finding indicating how the data conforms to these requirements.

(iv) The State may waive the final two quarters of initial monitoring for perchlorate for a sampling point if the results of the samples from the previous two quarters are below the detection limit.

*****

(i)***

(3) Compliance with the maximum contaminant level for nitrate, nitrite and perchlorate is determined based on one sample if the levels of these contaminants are below the MCLs. If the level of perchlorate exceeds the MCL in the initial sample, a confirmation sample is required in accordance with paragraph 141.23(f)(1) and compliance shall be

based on the average of the initial and confirmation sample. If the levels of nitrate and/or nitrite exceed the MCLs in the initial sample, a confirmation sample is required in accordance with paragraph 141.23(f)(2) and compliance shall be based on the average of the initial and confirmation sample.

*****

(k)***

(1) Analysis for the following contaminants shall be conducted in accordance with the methods in the following table, or the alternative methods listed in Appendix A to subpart C of this part, or their equivalent as determined by the EPA.

*****

Contaminant	Methodology[13]	EPA	ASTM[3]	SM[4] (18th, 19th ed.)	SM[4] (20th ed.)	SM Online[22]	Other
******	******	*******	*******	*******	*******	*******	*******
Perchlorate	Ion Chromatography	314.0					
	Inline Column Concentration/Matrix Elimination Ion Chromatography with Suppressed Conductivity Detection	314.1					
	Two-Dimensional Ion Chromatography with Suppressed	314.2					

	Conductivity Detection Liquid Chromatography Electrospray Ionization Mass Spectrometry Ion Chromatography with Suppressed Conductivity and Electrospray Ionization Mass Spectrometry	 331.0 332.0					
******	*******	*******	*******	*******	*******	*******	*******

*****

[3]Annual Book of ASTM Standards, ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428, http://www.astm.org.; Annual Book of ASTM Standards 1994, Vols. 11.01 and 11.02; Annual Book of ASTM Standards 1996, Vols. 11.01 and 11.02; Annual Book of ASTM Standards 1999, Vols. 11.01 and 11.02; Annual Book of ASTM Standards 2003, Vols. 11.01 and 11.02.

*****

[4]Standard Methods for the Examination of Water and Wastewater, American Public Health Association, 800 I Street NW., Washington, DC 20001-3710; Standard Methods for the Examination of Water and Wastewater, 18th edition (1992); Standard Methods for the Examination of Water and Wastewater, 19th edition (1995); Standard Methods for the

Examination of Water and Wastewater, 20th edition (1998).The following methods from this edition cannot be used: 3111 B, 3111 D, 3113 B, and 3114 B.

*****

[13]Because MDLs reported in EPA Methods 200.7 and 200.9 were determined using a 2x preconcentration step during sample digestion, MDLs determined when samples are analyzed by direct analysis (i.e., no sample digestion) will be higher. For direct analysis of cadmium and arsenic by Method 200.7, and arsenic by Method 3120 B, sample preconcentration using pneumatic nebulization may be required to achieve lower detection limits. Preconcentration may also be required for direct analysis of antimony, lead, and thallium by Method 200.9; antimony and lead by Method 3113 B; and lead by Method D3559-90D, unless multiple in-furnace depositions are made.

*****

[22]Standard Methods Online, American Public Health Association, 800 I Street NW., Washington, DC 20001, available at http://www.standardmethods.org. The year in which each method was approved by the Standard Methods Committee is designated by the last two digits in the method number. The methods listed are the only online versions that may be used.

*****

(2)***

Contaminant	Preservative[1]	Container[2]	Time[3]

*******	*******	*******	*******
Perchlorate[7]	4 °C	P or G	28 days
*******	*******	*******	******

[1]For cyanide determinations samples must be adjusted with sodium hydroxide to pH 12 at the time off collection. When chilling is indicated the sample must be shipped and stored at 4 °C or less. Acidification of nitrate or metals samples may be with a concentrated acid or a dilute (50% by volume) solution of the applicable concentrated acid. Acidification of samples for metals analysis is encouraged and allowed at the laboratory rather than at the time of sampling provided the shipping time and other instructions in Section 8.3 of EPA Methods 200.7 or 200.8 or 200.9 are followed.

[2]P = plastic, hard or soft; G = glass, hard or soft.

[3]In all cases samples should be analyzed as soon after collection as possible. Follow additional (if any) information on preservation, containers or holding times that is specified in method.

*****

[7] Sample collection for perchlorate shall be conducted following the requirements specified in the approved methods in 141.23(k)(1) or the alternative methods listed in appendix A of subpart C of this part, or their equivalent as determined by the EPA.

*****

(3)***

(ii)***

Contaminant	Acceptance limit
*******	*******
Perchlorate	±20% at ≥0.004 mg/L
*******	*******

*****

Subpart F—Maximum Contaminant Level Goals and Maximum Residual Disinfectant Level Goals

*****

§141.51 Maximum contaminant level goals for inorganic contaminants.

*****

(b)***

Contaminant	MCLG (mg/l)
*******	*******
Perchlorate	0.056
*******	*******

*****

Subpart G—National Primary Drinking Water Regulations: Maximum Contaminant Levels and Maximum Residual Disinfectant Levels

§141.60 Effective dates.

(a) ***

(5) The effective date for §141.62(b)(17) is [insert date].

§141.62 Maximum contaminant levels for inorganic contaminants.

*****

(b)***

Contaminant	MCL (mg/l)
*******	*******
(17) Perchlorate	0.056

(c)***

BAT FOR INORGANIC COMPOUNDS LISTED IN SECTION 141.62(b)

Chemical Name	BAT(s)
*******	********
Perchlorate	5, 7, 14
*******	*******

*****

Key to BATs in Table

*****

5 = Ion Exchange

*****

7 = Reverse Osmosis

*****

14 = Biological Treatment

*****

(e)The Administrator, pursuant to section 1412 of the Act, hereby identified in the following table the affordable technology, treatment technique, or other means available to systems serving 10,000 persons or fewer for achieving compliance with the maximum contaminant level for perchlorate:

SMALL SYSTEM COMPLIANCE TECHNOLOGIES (SSCTs) FOR PERCHLORATE

Small system compliance technology	Affordability for listed small system categories
Ion exchange	All size categories.
Reverse osmosis (point of use)	All size categories

Subpart O – Consumer Confidence Reports

*****

APPENDIX A TO SUBPART O OF 141 – REGUATED CONTAMINANTS

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
********	*******	*******	*******	*******	*******	*******
Inorganic contaminants						
********	********	********	*******	*******	*******	*******

Perchlorate	0.056	1000	56	56	Perchlorate is commonly used in solid rocket propellants, munitions, fireworks, airbag initiators for vehicles, matches and signal flares. Perchlorate may occur naturally, particularly in arid regions such as the southwestern United States and is found as a natural impurity in nitrate salts used to produce nitrate fertilizers, explosives and other products.	Offspring of pregnant women and infants who drink water containing perchlorate in excess of the MCL could experience delays in their physical or mental development.
*******	*******	*******	*******	*******	*******	*******

Subpart Q – Public Notification of Drinking Water Violations

*****

APPENDIX A TO SUBPART Q OF PART 141 – NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE[1]

Contaminant	MCL/MRDL/TT violations[2]		Monitoring & testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
*******				
B. Inorganic Chemicals (IOCs)				

*******				
14. Perchlorate	1	141.62(b)	3	141.23(a), (c), 141.23(f)(1)
*******				

[1] Violations and other situations not listed in this table (e.g., failure to prepare Consumer Confidence Reports), do not require notice, unless otherwise determined by the primacy agency. Primacy agencies may, at their option, also require a more stringent public notice tier (e.g., Tier 1 instead of Tier or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under 141.202(a) and 141.203(a).

[2] MCL-Maximum contaminant level, MDRL-Maximum residual disinfectant level, TT-treatment technique

*****

APPENDIX B TO SUBPART Q OF PART 141 – STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
*******			
C. Inorganic Chemicals (IOCs)			
*******	*******	*******	*******
21. Perchlorate	0.056	0.056	Offspring of pregnant women and infants who drink water containing perchlorate in excess of the MCL could experience delays in their physical or mental development.
*******	*******	*******	*******

[1] MCLG – Maximum contaminant level goal

[2] MCL – Maximum contaminant level

PART 142 - NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

1. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9, and 300j-11.

2. In § 142.62:

a. Add an entry for "Perchlorate" to the table in paragraph (b); and

b. Add entry "14 = Biological Treatment" in the table's *Key to BATs* in paragraph (b).

Subpart G – Identification of Best Technology, Treatment Techniques or Other Means Generally Available.

*****

§142.62 Variances and exemptions from the maximum contaminant levels for organic and inorganic chemicals.

*****

(b)***

BAT FOR INORGANIC COMPOUNDS LISTED IN §141.62(b)

Chemical Name	BAT(s)
*******	********
Perchlorate	5, 7, 14
*******	*******

*****

Key to BATs in Table

*****

5 = Ion Exchange

*****

7 = Reverse Osmosis

*****

14 = Biological Treatment

*****

Message

From: Burneson.Eric@epa.gov [Burneson.Eric@epa.gov]
Sent: 4/5/2019 9:25:52 PM
To: Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
Subject: Fwd: Perchlorate
Attachments: Perchlorate Proposed NPDWR Redline 4-5-19.docx; ATT00001.htm

FYI Jennifer has a few more edits so use this version.

Sent from my iPhone

Begin forwarded message:

> **From:** "Mclain, Jennifer" <Mclain.Jennifer@epa.gov>
> **Date:** April 5, 2019 at 5:24:02 PM EDT
> **To:** "Ross, David P" <ross.davidp@epa.gov>, "Forsgren, Lee" <Forsgren.Lee@epa.gov>
> **Cc:** "Wildeman, Anna" <wildeman.anna@epa.gov>, "Kramer, Jessica L." <kramer.jessical@epa.gov>, "McDonough, Owen" <mcdonough.owen@epa.gov>, "Burneson, Eric" <Burneson.Eric@epa.gov>, "Tiago, Joseph" <Tiago.Joseph@epa.gov>, "Aguirre, Janita" <Aguirre.Janita@epa.gov>, "Mejias, Melissa" <mejias.melissa@epa.gov>, "Guilaran, Yu-Ting" <Guilaran.Yu-Ting@epa.gov>
> **Subject: Perchlorate**
>
> Internal/deliberative
>
> Dave & Lee
>
> Before OGWDW formally submits the revised draft Perchlorate Proposed NPDWR package to OW, I wanted you to see a version highlighting the substantive changes we made as a result of our conversations over the past month. Please let us know if you have any recommended changes.
>
> Thanks
> Jennifer
>
> Jennifer L McLain
> Deputy Director
> Office of Ground Water and Drinking Water
> U.S. EPA
> 202-564-4029

[FILENAME * MERGEFORMAT]

ENVI RONMENTAL PROTECTION AGENCY

40 CFR Parts 141, and 142

[EPA-HQ-OW-2018-0780; FRL-XXXX-XX-OW]

RIN 2040-AF28

National Primary Drinking Water Regulations: Proposed Perchlorate Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule, request for public comment.

SUMMARY: The Environmental Protection Agency (EPA) is proposing a drinking water regulation for perchlorate and a health-based Maximum Contaminant Level Goal (MCLG) in accordance with the Safe Drinking Water Act (SDWA). The EPA is proposing to set both the enforceable Maximum Contaminant Level (MCL) for the perchlorate regulation and the perchlorate MCLG at 0.056 mg/L (56 μg/L). The EPA is proposing requirements for water systems to conduct monitoring and reporting for perchlorate and to provide information about perchlorate to their consumers through public notification and consumer confidence reports. This proposal includes requirements for primacy agencies that implement the public water system supervision program under the SDWA. This proposal also includes a list of treatment

technologies that would enable water systems to comply with the MCL, including affordable compliance technologies for small systems serving 10,000 persons or less.

In addition to the proposed regulation, EPA is requesting comment upon ~~two~~three alternatives: 1) whether the MCL and MCLG for perchlorate should be set at 0.018 mg/L (18 µg/L), 2) whether the MCL and MCLG for perchlorate should be set at 0.090 mg/L (90 µg/L), or ~~2~~3) whether instead of issuing a national primary drinking water regulation the EPA should withdraw the Agency's February 11, 2011 determination to regulate perchlorate in drinking water. Under this alternative, the final action would be a withdrawal of the determination to regulate and there would be no MCLG or national primary drinking water regulation for perchlorate.

DATES: Comments must be received on or before *[insert date 60 days after publication in the* Federal Register*]***.** Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before *[insert date 30 days after date of publication in the* Federal Register*]*.

ADDRESSES: Submit your comments, identified by Docket ID No. **EPA-HQ-OW-2018-0780**, at [HYPERLINK "http://www.regulations.gov"]. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit [HYPERLINK "http://www2.epa.gov/dockets/commenting-epa-dockets"].

FOR FURTHER INFORMATION CONTACT: Samuel Hernandez, Office of Ground Water and Drinking Water, Standards and Risk Management Division (Mail Code 4607M), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone number: (202) 564-1735; email address: hernandez.samuel@epa.gov.

SUPPLEMENTARY INFORMATION: This proposed rule is organized as follows:

I. General Information

A. What is the EPA Proposing?

B. Does This Action Apply to Me?

II. Background

A. What is Perchlorate?

B. Statutory Authority

C. Regulatory History

III. Health Effects of Perchlorate

A. 2008 Preliminary Regulatory Determinations

B. 2009 Supplemental Request for Comment and 2011 Final Regulatory Determination

C. Science Advisory Board Recommendations

D. Perchlorate Model Development and Peer Reviews

E. Identification of the Sensitive Population

F. BBDR Model Specification for the Sensitive Population

G. Epidemiological Literature

H. Translate POD to RfD

I. Translate RfD into an MCLG

IV. Maximum Contaminant Level Goal and Alternative

V. Maximum Contaminant Level and Alternative

VI. Occurrence

VII. Analytical Methods

VIII. Monitoring and Compliance Requirements

A. What are the Monitoring Requirements?

B. Can States Grant Monitoring Waivers?

C. How are System MCL Violations Determined?

D. When Must Systems Complete Initial Monitoring?

E. Can Systems Use Grandfathered Data to Satisfy the Initial Monitoring Requirement?

IX. Safe Drinking Water Act Right to Know Requirements

A. What are the Consumer Confidence Report Requirements?

B. What are the Public Notification Requirements?

X. Treatment Technologies

A. What are the Best Available Technologies?

B. What are the Small System Compliance Technologies?

XI. Rule Implementation and Enforcement

A. What are the Requirements for Primacy?

B. What are the State Record Keeping Requirements?

C. What are the State Reporting Requirements?

XII. Health Risk Reduction Cost Analysis

A. Identifying Affected Entities

B. Method for Estimating Costs

C. Method for Estimating Benefits

D. Comparison of Costs and Benefits

XIII. Uncertainty Analysis

XIV. Request for Comment on Proposed Rule

XV. Request for Comment on Potential Regulatory Determination Withdrawal

XVI. Administrative Requirements

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563 Improving Regulation and Regulatory Review

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

C. Paperwork Reduction Act

D. Regulatory Flexibility Act (RFA)

E. Unfunded Mandates Reform Act

F. Executive Order 13132: Federalism

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

H. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks

I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

J. National Technology Transfer and Advancement Act of 1995

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. What is the EPA Proposing?

This action contains a proposal and ~~two~~three alternatives for public comment. First, the EPA proposes to establish a Maximum Contaminant Level Goal (MCLG) and National Primary Drinking Water Regulations (NPDWR) for perchlorate in public water supplies. The EPA proposes an MCLG of ~~0.056 mg~~56 µg/L, and to regulate perchlorate in drinking water at an enforceable maximum contaminant level (MCL) of ~~0.056 mg~~56 µg/L.

The EPA is proposing a national primary drinking water regulation for perchlorate in accordance with its February 11, 2011 (76 FR 7762) determination to regulate perchlorate under the SDWA. Based on the best available peer reviewed science at that time, the EPA found that perchlorate met the SDWA's three criteria for regulating a contaminant: 1) the contaminant may have an adverse effect on the health of persons, 2) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems (PWSs) with a frequency and at levels of public health concern, and 3) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

Second, as explained in more detail below, the EPA is proposing ~~an~~two alternative ~~MCL/~~MCLG/MCL values of ~~0.018 mg~~18 µg/L~~.~~ and 90 µg/L respectively. Third, because of the low levels of occurrence of perchlorate at the levels of concern, this action also discusses and requests comment on an alternative action under which EPA would withdraw its determination to regulate perchlorate. Under this alternative, there would be no MCLG or national primary drinking water regulation for perchlorate.

B. Does This Action Apply to Me?

Entities that could potentially be affected include the following:

Category	Examples of potentially affected entities
Public water systems	Community water systems Non-transient, non-community water systems
State and tribal agencies	Agencies responsible for drinking water regulatory development and enforcement

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that could be affected by this action. To determine whether your facility or activities could be affected by this action, you should carefully examine this proposed rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the FOR FURTHER INFORMATION CONTACT section.

II. Background

A. What is Perchlorate?

Perchlorate is a negatively charged inorganic ion that is comprised of one chlorine atom bound to four oxygen atoms, which is highly stable and mobile in the aqueous environment. Perchlorate comes from both natural and manmade sources. It is formed naturally via atmospheric processes and can be found within mineral deposits in certain geographical areas. It is also produced in the United States, and the most common compounds include ammonium perchlorate and potassium perchlorate, used primarily as oxidizers in solid fuels to power rockets, missiles, and fireworks.

B. Statutory Authority

Section 1412(b)(1)(A) of the SDWA requires the EPA to establish NPDWRs for contaminants that may have an adverse effect on the health of persons; that are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and where in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

C. Regulatory History

This section describes the process that led the Agency to propose an NPDWR for perchlorate. The SDWA requires the EPA to make determinations every five years whether to regulate at least five contaminants on the Contaminant Candidate List (CCL). The CCL is a list of drinking water contaminants that are known to occur in public water systems and are not currently subject to the EPA drinking water regulations. The EPA uses the CCL to identify priority contaminants for regulatory decision-making and information collection. Contaminants listed on the CCL may require future regulation under the SDWA. The EPA included perchlorate on the first, second, and third CCLs published in 1998, 2005, and 2009.

Once listed on the CCL, the Agency continues to collect data and encourage further research on CCL contaminants to better understand their potential health effects and to determine the levels at which they occur in drinking water. Section 1412(b)(1)(B)(ii) requires that, every five years, the EPA, after public comment, issue a determination whether or not to regulate at least five contaminants on the CCL. For any contaminant that the EPA determines meets the criteria for regulation, under Section 1412(b)(1)(E), the EPA must issue a proposed national primary drinking water regulation within two years and issue a final regulation 18 months after the proposal (which may be extended by 9 months).

Under Section 1412(b)(1)(B)(ii), the EPA must consider the occurrence data collected through the Unregulated Contaminant Monitoring Rule (UCMR). Between 2001 and 2005, the EPA required all large systems serving more than 10,000 people and a representative sample of small systems to monitor for perchlorate and 25 other contaminants under the first UCMR cycle (UCMR 1). Occurrence data generated through UCMR 1 is discussed further below.

To better understand the health effects of perchlorate, the EPA and other federal agencies asked the National Research Council (NRC) to evaluate the health implications of perchlorate ingestion. The NRC concluded that perchlorate exposure inhibits the transport of iodide[1] into the thyroid by the NIS, which may lead to decreases in T3 and T4 and increases in TSH [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a1mn5hjprkt","properties":{"formattedCitation":"(National Research Council (NRC), 2005b)","plainCitation":"(National Research Council (NRC), 2005b)","noteIndex":0},"citationItems":[{"id":350,"uris":["http://zotero.org/groups/945096/items/TN6HMC9D"],"uri":["http://zotero.org/groups/945096/items/TN6HMC9D"],"itemData":{"id":350,"type":"book","title":"Health Implications of Perchlorate Ingestion","publisher":"National Academies Press","publisher-place":"Washington, DC","event-place":"Washington, DC","author":[{"literal":"National Research Council (NRC)"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Additionally, the NRC concluded that the most sensitive population to perchlorate exposure are "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" (p. 178). The NRC recommended, and the EPA adopted, a reference dose (RfD) of 0.7 μg/kg/day. A reference dose is an estimate of a daily exposure to humans that is likely to be without an appreciable risk of adverse effects during a

[1] For the purposes of this FRN, "iodine" will be used to refer to dietary intake before entering the body. Once in the body, "iodide" will be used to refer to the ionic form.

lifetime. This RfD was based on a study [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"a3u94lt6me","properties":{"formattedCitation":"(Greer, Goodman, Pleus, & Greer, 2002)","plainCitation":"(Greer, Goodman, Pleus, & Greer, 2002)","noteIndex":0},"citationItems":[{"id":387,"uris":["http://zotero.org/groups/945096/items/6AKUNIX6"],"uri":["http://zotero.org/groups/945096/items/6AKUNIX6"],"itemData":{"id":387,"type":"article-journal","title":"Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans","container-title":"Environmental Health Perspectives","page":"927","volume":"110","issue":"9","author":[{"family":"Greer","given":"Monte A."},{"family":"Goodman","given":"Gay"},{"family":"Pleus","given":"Richard C."},{"family":"Greer","given":"Susan E."}],"issued":{"date-parts":[["2002"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] of perchlorate's inhibition of radioactive iodine uptake in healthy adults and the application of an uncertainty factor of 10 for intraspecies variability [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"0oHz805e","properties":{"formattedCitation":"(USEPA, 2005b)","plainCitation":"(USEPA, 2005b)","noteIndex":0},"citationItems":[{"id":980,"uris":["http://zotero.org/groups/945096/items/LHANJBR6"],"uri":["http://zotero.org/groups/945096/items/LHANJBR6"],"itemData":{"id":980,"type":"article","title":"Integrated Risk Information System (IRIS) Chemical Assessment

Summary: Perchlorate (ClO4-) and Perchlorate Salts","publisher":"USEPA National Center for Environmental Assessment","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2005"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

In October 2008, the EPA published a preliminary regulatory determination not to regulate perchlorate in drinking water and requested public comment (73 FR 60262). In that preliminary determination, the EPA tentatively concluded that perchlorate did not occur with a frequency and at levels of public health concern and that development of a regulation did not present a meaningful opportunity for health risk reduction for persons served by public water systems. The EPA derived and used a Health Reference Level (HRL) of 15 μg/L based on the RfD of 0.7 μg/kg/day in making this conclusion [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"FZ6WMtAv","properties":{"formattedCitation":"(USEPA, 2008a)","plainCitation":"(USEPA, 2008a)","noteIndex":0},"citationItems":[{"id":934,"uris":["http://zotero.org/groups/945096/items/HBX88QM9"],"uri":["http://zotero.org/groups/945096/items/HBX88QM9"],"itemData":{"id":934,"type":"article-journal","title":"Drinking water: Preliminary regulatory determination on perchlorate","container-title":"Federal Register","volume":"73","issue":"198","abstract":"SUMMARY: This action presents EPA's preliminary regulatory determination for perchlorate in accordance with the Safe Drinking Water Act (SDWA). The Agency has determined that a national primary drinking water regulation

(NPDWR) for perchlorate would not present \"a meaningful opportunity for health risk reduction for persons served by public water systems." The SDWA requires EPA to make determinations every five years of whether to regulate at least five contaminants on the Contaminant Candidate List (CCL). EPA included perchlorate on the first and second CCLs that were published in the Federal Register on March 2, 1998 and February 24, 2005. Most recently, EPA presented final regulatory determinations regarding 11 contaminants on the second CCL in a notice published in the Federal Register on July 30, 2008. In today's action, EPA presents supporting rationale and requests public comment on its preliminary regulatory determination for perchlorate. EPA will make a final regulatory determination for perchlorate after considering comments and information provided in the 30-day comment period following this notice. EPA plans to publish a health advisory for perchlorate at the time the Agency publishes its final regulatory determination to provide State and local public health officials with technical information that they may use in addressing local contamination.","ISSN":"ISSN 0097-6326 EISSN 2167-2520","shortTitle":"Federal Register","journalAbbreviation":"Fed. Reg.","language":"English","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2008"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Using this health reference level of 15 µg/L the EPA also published an interim health advisory (HA) for perchlorate. HAs, which are not regulations, contain recommended concentrations of drinking water contaminants at which adverse health effects are not anticipated to occur over specific exposure durations. For perchlorate, the health advisory was developed for subchronic exposure (USEPA 2008d).

In August 2009, the EPA published a supplemental request for comment with a new analysis that derived potential alternative HRLs for 14 life stages, including infants and children. The analysis used the RfD of 0.7 μg/kg/day and the life stage-specific bodyweight and exposure information [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"XzGawKtq","properties":{"formattedCitation":"(USEPA, 2009a)","plainCitation":"(USEPA, 2009a)","noteIndex":0},"citationItems":[{"id":309,"uris":["http://zotero.org/groups/945096/items/ILBCYL66"],"uri":["http://zotero.org/groups/945096/items/ILBCYL66"],"itemData":{"id":309,"type":"report","title":"Inhibition of the Sodium-Iodide Symporter By Perchlorate: An Evaluation of Lifestage Sensitivity Using Physiologically Based Pharmacokinetic (PBPK) Modeling (Final Report)","collection-title":"EPA/600/R-08/106A","publisher-place":"Washington, D.C.","event-place":"Washington, D.C.","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2009"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

After considering comments on the October 2008 and August 2009 notices, the EPA made a final determination in February 2011 to regulate perchlorate in drinking water [ADDIN ZOTERO_ITEM CSL_CITATION

{"citationID":"E1I1fclP","properties":{"formattedCitation":"(USEPA, 2011a)","plainCitation":"(USEPA, 2011a)","noteIndex":0},"citationItems":[{"id":929,"uris":["http://zotero.org/groups/945096/items/4EFIN6HN"],"uri":["http://zotero.org/groups/945096/items/4EFIN6HN"],"itemData":{"id":929,"type":"webpage","title":"Drinking Water: Regulatory Determination on Perchlorate. Federal Register Notice. 76 FR No. 29. Pages 7762-7767. (February 11, 2011) (to be codified at 40 C.F.R pt. 141).","URL":"https://www.federalregister.gov/articles/2011/02/11/2011-2603/drinking-water-regulatory-determination-on-perchlorate","shortTitle":"Drinking Water: Regulatory Determination on Perchlorate. Federal Register Notice. 76 FR No. 29. Pages 7762-7767. (February 11, 2011) (to be codified at 40 C.F.R pt. 141).","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2011"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The Agency found that perchlorate may have an adverse effect on the health of persons, that it is known to occur in public drinking water systems with a frequency and at levels that present a public health concern, and in the judgment of the Administrator, regulation of perchlorate presented a meaningful opportunity for health risk reduction for persons served by public water systems. As a result of the determination, and as required by Section 1412(b)(1)(E), the EPA initiated the process to develop an MCLG and NPDWR for perchlorate as described in this notice.

In response to a lawsuit brought to enforce the deadlines in Section 1412(b)(1)(E), the U.S. District Court for the Southern District of New York entered a consent decree, requiring the EPA to propose an NPDWR with a proposed MCLG for perchlorate in drinking water no later than May 28, 2019, and finalize a NPDWR and MCLG for perchlorate in drinking water no later than December 19, 2019. The consent decree is available in the docket for today's proposed rule.

III. Health Effects

Perchlorate exposure may adversely affect human health (ATSDR 2008; SAB, 2013; Taylor et al., 2015). Specifically, perchlorate inhibits uptake of iodide into the thyroid gland by competitively binding to the protein that transports iodide from blood to the thyroid gland (Greer et al., 2002; NRC, 2005; ATSDR; 2008). Iodide is necessary for the synthesis of thyroid hormones and decreased iodide uptake into the thyroid can adversely affect thyroid hormone production (SAB, 2013; Blount et al., 2006; Steinmaus et al., 2007, 2013, 2016, McMullen et al., 2017; Knight et al., 2018). These changes in thyroid hormone levels in a pregnant woman may be linked to changes in the neurodevelopment of her offspring (SAB, 2013; Korevaar et al., 2016; Fan and Wu, 2016; Wang et al., 2016; Alexander et al., 2017; Thompson et al., 2018). In addition, alterations in thyroid homeostasis may impact other body systems including the reproductive (Alexander et al., 2017; Hou et al., 2016; Maraka et al., 2016) and cardiovascular systems (Asvold et al., 2012; Sun et al., 2017).

Exposure to perchlorate is known to inhibit the uptake of iodide by the thyroid gland. A sufficient inhibition of iodide uptake results in iodide deficiency within the thyroid. Given that thyroid hormones (triiodothyronine (T3) and thyroxine (T4)) require iodide for production, a decrease in intra-thyroidal iodide can result in decreased production of these hormones. This could in turn result in increased thyroid stimulating hormone (TSH), the hormone that acts on the thyroid gland to stimulate iodide uptake to increase thyroid hormone production [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"eF6zWm7L","properties":{"formattedCitation":"(ATSDR, 2008; Blount, Pirkle, Osterloh, Valentin-Blasini, & Caldwell, 2006; National Research Council (NRC), 2005; Steinmaus, Miller, Cushing, Blount, & Smith, 2013; Steinmaus et al., 2016)","plainCitation":"(ATSDR, 2008; Blount, Pirkle, Osterloh, Valentin-Blasini, & Caldwell, 2006; National Research Council (NRC), 2005; Steinmaus, Miller, Cushing, Blount, & Smith, 2013; Steinmaus et al., 2016)","noteIndex":0},"citationItems":[{"id":428,"uris":["http://zotero.org/groups/945096/items/UIANA947"],"uri":["http://zotero.org/groups/945096/items/UIANA947"],"itemData":{"id":428, "type":"bill","title":"Toxicological Profile for Perchlorates","author":[{"family":"ATSDR","given":""}],"issued":{"date-parts":[["2008"]]}}},{"id":203,"uris":["http://zotero.org/groups/945096/items/UW4TFPNI"],"uri ":["http://zotero.org/groups/945096/items/UW4TFPNI"],"itemData":{"id":203,"type":"article-journal","title":"Urinary perchlorate and thyroid tormone levels in adolescent and adult men and women living in the United States","container-title":"Environmental Health Perspectives","page":"1865-

1871","volume":"114","issue":"12","source":"CrossRef","DOI":"10.1289/ehp.9466","ISSN":"0091-6765","language":"en","author":[{"family":"Blount","given":"Benjamin C."},{"family":"Pirkle","given":"James L."},{"family":"Osterloh","given":"John D."},{"family":"Valentin-Blasini","given":"Liza"},{"family":"Caldwell","given":"Kathleen L."}],"issued":{"date-parts":[["2006"]]}}},{"id":349,"uris":["http://zotero.org/groups/945096/items/TN6HMC9D"],"uri":["http://zotero.org/groups/945096/items/TN6HMC9D"],"itemData":{"id":349,"type":"book","title":"Health Implications of Perchlorate Ingestion","publisher":"National Academies Press","publisher-place":"Washington, DC","event-place":"Washington, DC","author":[{"literal":"National Research Council (NRC)"}],"issued":{"date-parts":[["2005"]]}}},{"id":39,"uris":["http://zotero.org/groups/945096/items/35VPNIKR"],"uri":["http://zotero.org/groups/945096/items/35VPNIKR"],"itemData":{"id":39,"type":"article-journal","title":"Combined effects of perchlorate, thiocyanate, and iodine on thyroid function in the national health and nutrition examination survey 2007-8","container-title":"Environmental research","volume":"123","source":"www.ncbi.nlm.nih.gov","abstract":"Perchlorate, thiocyanate, and low iodine intake can all decrease iodide intake into the thyroid gland. This can reduce thyroid hormone production since iodide is a key component of thyroid hormone. Previous research has suggested that each of these factors ...","URL":"https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3857960/","DOI":"10.1016/j.envres.2013.01.005","note":"PMID:

23473920","language":"en","author":[{"family":"Steinmaus","given":"Craig"},{"family":"Miller","given":"Mark D."},{"family":"Cushing","given":"Lara"},{"family":"Blount","given":"Benjamin C."},{"family":"Smith","given":"Allan H."}],"issued":{"date-parts":[["2013",5]]},"accessed":{"date-parts":[["2017",5,5]]}}},{"id":211,"uris":["http://zotero.org/groups/945096/items/H4FH49VS"],"uri":["http://zotero.org/groups/945096/items/H4FH49VS"],"itemData":{"id":211,"type":"article-journal","title":"Thyroid hormones and moderate exposure toperchlorate during pregnancy in women in southern California","container-title":"Environmental Health Perspectives","page":"861-867","volume":"124","issue":"6","source":"PubMed","abstract":"BACKGROUND: Findings from national surveys suggest that everyone in the United States is exposed to perchlorate. At high doses, perchlorate, thiocyanate, and nitrate inhibit iodide uptake into the thyroid and decrease thyroid hormone production. Small changes in thyroid hormones during pregnancy, including changes within normal reference ranges, have been linked to cognitive function declines in the offspring.\nOBJECTIVES: We evaluated the potential effects of low environmental exposures to perchlorate on thyroid function.\nMETHODS: Serum thyroid hormones and anti-thyroid antibodies and urinary perchlorate, thiocyanate, nitrate, and iodide concentrations were measured in 1,880 pregnant women from San Diego County, California, during 2000-2003, a period when much of the area's water supply was contaminated from an

industrial plant with perchlorate at levels near the 2007 California regulatory standard of 6 μg/L. Linear regression was used to evaluate associations between urinary perchlorate and serum thyroid hormone concentrations in models adjusted for urinary creatinine and thiocyanate, maternal age and education, ethnicity, and gestational age at serum collection.\nRESULTS: The median urinary perchlorate concentration was 6.5 μg/L, about two times higher than in the general U.S.\nPOPULATION: Adjusted associations were identified between increasing log10 perchlorate and decreasing total thyroxine (T4) [regression coefficient (β) = -0.70; 95% CI: -1.06, -0.34], decreasing free thyroxine (fT4) (β = -0.053; 95% CI: -0.092, -0.013), and increasing log10 thyroid-stimulating hormone (β = 0.071; 95% CI: 0.008, 0.133).\nCONCLUSIONS: These results suggest that environmental perchlorate exposures may affect thyroid hormone production during pregnancy. This could have implications for public health given widespread perchlorate exposure and the importance of thyroid hormone in fetal neurodevelopment.\nCITATION: Steinmaus C, Pearl M, Kharrazi M, Blount BC, Miller MD, Pearce EN, Valentin-Blasini L, DeLorenze G, Hoofnagle AN, Liaw J. 2016. Thyroid hormones and moderate exposure to perchlorate during pregnancy in women in Southern California. Environ Health Perspect 124:861-867;
http://dx.doi.org/10.1289/ehp.1409614.","DOI":"10.1289/ehp.1409614","ISSN":"1552-9924","note":"PMID: 26485730\nPMCID: PMC4892913","journalAbbreviation":"Environ. Health
Perspect.","language":"eng","author":[{"family":"Steinmaus","given":"Craig"},{"family":"Pearl

","given":"Michelle"},{"family":"Kharrazi","given":"Martin"},{"family":"Blount","given":"Benjamin C."},{"family":"Miller","given":"Mark D."},{"family":"Pearce","given":"Elizabeth N."},{"family":"Valentin-Blasini","given":"Liza"},{"family":"DeLorenze","given":"Gerald"},{"family":"Hoofnagle","given":"Andrew N."},{"family":"Liaw","given":"Jane"}],"issued":{"date-parts":[["2016",6]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. For populations with developing brains (e.g., fetuses, neonates, and children), disruptions in homeostatic thyroid hormone function can result in adverse neurodevelopmental effects (Alexander et al., 2017; Glinoer & Delange, 2000; Glinoer & Rovet, 2009; SAB for the U.S. EPA, 2013). Specifically, decreased maternal thyroid hormone levels during pregnancy, including in the hypothyroxinemic range[2], have been linked to many adverse neurodevelopmental outcomes in offspring, including IQ decrements, schizophrenia, ADHD, expressive language delay, reduced school performance, autism, and delayed cognitive development (Alexander et al., 2017; Ghassabian, Bongers-Schokking,

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[2] Maternal hypothyroxinemia is defined as TSH in the reference range and fT4 in the lower percentiles. The SAB notes that hypothyroxinemia has been defined by a "variety of cutoffs…ranging from fT4 below the 10th or 5th percentiles to below the 2.5th percentile" [ADDIN EN.CITE <EndNote><Cite><Author>SAB</Author><Year>2013</Year><RecNum>50</RecNum><Pages>10</Pages><DisplayText>(SAB, 2013, p. 10)</DisplayText><record><rec-number>50</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1437138201">50</key></foreign-keys><ref-type name="Government Document">46</ref-type><contributors><authors><author>SAB,</author></authors><secondary-authors><author>U.S. Environmental Protection Agency,</author></secondary-authors></contributors><titles><title>Advice on approaches to derive a maximum contaminant level goal for perchlorate. EPA-SAB-13-004</title></titles><dates><year>2013</year></dates><pub-location>Washington, DC</pub-location><urls></urls></record></Cite></EndNote>] ~~in the population~~ (SAB, 2013, p.10) in the population.

Henrichs, Jaddoe, & Visser, 2011; Gyllenberg et al., 2016; Henrichs et al., 2010; Korevaar et al., 2016, Noten et al., 2015; Pop et al., 2003, 1999; SAB for the U.S. EPA, 2013; van Mil et al., 2012).

The Agency's understanding of the effects of perchlorate on health has evolved over time with improved research and modeling capabilities. The following sections describe information sources the EPA used in its assessment as well as the regulatory process followed by the Agency in its decision making.

*A.	2008 Preliminary Regulatory Determination*

In 2005, at the request of the EPA and other federal agencies, the NRC evaluated the health implications of perchlorate ingestion. The NRC concluded that perchlorate exposure could inhibit the transport of iodide into the thyroid, leading to thyroid hormone deficiency (NRC, 2005). A significant inhibition of iodide uptake results in intra-thyroid iodide deficiency, decreased synthesis of key thyroid hormones (triiodothyronine (T3) and thyroxine (T4)), and increased thyroid stimulating hormone (TSH). The NRC also concluded that a prolonged decrease of thyroid hormones is potentially more likely to have adverse effects in sensitive populations (e.g., the fetuses of pregnant women who might have hypothyroidism or iodide deficiency).

Based on NRC's recommendations, the EPA adopted a perchlorate reference dose (RfD) of 0.7 μg/kg/day in 2005 (U.S. EPA, 2005). This value was based on a no observed effect level (NOEL) of 7 μg/kg/day identified from a study (Greer, Goodman, Pleus, & Greer, 2002) of perchlorate's inhibition of radioactive iodine uptake in healthy adults and the application of an uncertainty factor of 10 for intraspecies variability.

The EPA derived an HRL of 15 µg/L using the RfD of 0.7 µg/kg/day, a default bodyweight of 70 kg, a default drinking water consumption rate of 2 L/day, and a perchlorate-specific relative source contribution (RSC) of 62 percent that was derived for a pregnant woman (USEPA, 2008a) (73 FR 60262). The RSC is the percentage of the RfD remaining for drinking water after other sources of exposure to perchlorate (primarily food) have been considered. The EPA's HRL was calculated to offer a margin of protection against adverse health effects to the most sensitive population, fetuses during pregnancy.

On October 10, 2008, the EPA published a preliminary negative regulatory determination for perchlorate and requested public comment on its determination that a NPDWR for perchlorate would not present a meaningful opportunity for health risk reduction for persons served by public water systems. The EPA estimated that less than 1% of drinking water systems had perchlorate levels above the HRL of 15 µg/L. Therefore, the Agency determined that perchlorate did not occur frequently at levels of health concern. The EPA also determined that there was not a meaningful opportunity for a NPDWR to reduce health risks.

In December 2008, the EPA issued an interim health advisory (15 µg/L perchlorate in drinking water) to provide guidance to State and local officials in their efforts to address perchlorate contamination in drinking water (U.S. EPA, 2008d).

B. 2009 Supplemental Request for Comment and 2011 Final Regulatory Determination

The EPA received over 33,000 comments in response to its 2008 preliminary determination to not regulate perchlorate (USEPA, 2011a). After reviewing the comments, the EPA developed alternative HRLs for other sensitive subpopulations in addition to fetuses of pregnant women. The EPA developed alternative HRLs for 14 life stages including infants and children. The EPA also evaluated the occurrence of perchlorate at levels above these alternative HRLs using the UCMR 1 occurrence data.

The analysis used the RfD of 0.7 μg/kg/day and life stage-specific bodyweight and exposure information (i.e., drinking water intake, RSC) for each of the 14 life stages evaluated. The resulting HRLs ranged from 1 μg/L to 47 μg/L. In August 2009, the EPA published a supplemental request for comment with the new analysis and HRLs (74 FR 41883; USEPA, 2009a). After careful consideration of public comments, on February 11, 2011, the EPA published its final determination to regulate perchlorate (76 FR 7762; USEPA, 2011a).

C. Science Advisory Board Recommendations

As required by Section 1412(d), as part of the national primary drinking water regulatory development process, the EPA requested comments from the Science Advisory Board (SAB) in 2012, seeking guidance on how best to consider and interpret the life stage information, the epidemiologic and biomonitoring data since the NRC report, physiologically-based pharmacokinetic (PBPK) analyses, and the totality of perchlorate health information to derive an MCLG for perchlorate. The SAB recommended the following:

- Derive a perchlorate MCLG that addresses sensitive life stages through physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling based upon perchlorate's mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters;
- Expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;
- Utilize a mode-of-action framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition – to thyroid hormone changes – and finally to neurodevelopmental impacts; and
- "Extend the [BBDR] model expeditiously to…provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages" (SAB for the U.S. EPA, 2013, p. 19).

This SAB-proposed framework would incorporate the previous endpoint of iodide uptake inhibition that was the basis for the RfD as part of a broader and more comprehensive framework that links perchlorate exposure to adverse neurodevelopmental outcomes. It also focuses on the smaller changes in thyroid hormones (specifically fT4) that are associated with maternal hypothyroxinemia and subsequent adverse neurodevelopmental health effects rather than the significant changes in thyroid hormones (both fT4 and TSH) that are associated with hypothyroidism.

D. Perchlorate Model Development and Peer Review

To address the SAB recommendations, the EPA revised the existing PBPK/PD models (Lumen, Mattie, & Fisher, 2013; U.S. EPA, 2009b) to create a Biologically Based Dose Response (BBDR) model that predicts changes in thyroid hormone (i.e., T4, fT4, and T3) levels as a result of nutritional iodine intake and perchlorate exposure in women prior to pregnancy and in early gestation. The EPA developed BBDR models that included all sensitive life stages identified by the SAB, i.e., the fetus (by modeling a pregnant mother at 40 gestational weeks), neonates, and infants (SAB for the U.S. EPA, 2013, p. 19), with the pregnancy model representing the third trimester.

To assure that the Agency had implemented the SAB recommendations for modeling thyroid hormone changes, the EPA convened an independent peer review panel to evaluate the BBDR models in 2017 (External Peer Reviewers for USEPA, 2017). Reviewers stressed the importance of developing an early pregnancy model when considering adverse neurodevelopmental impacts given the fetuses lack of a functioning thyroid gland until approximately 16 gestational weeks [ADDIN EN.CITE <EndNote><Cite><Author>Morreale de Escobar</Author><Year>2004</Year><RecNum>49</RecNum><DisplayText>(G Morreale de Escobar, Obregón, & Escobar del Rey, 2004)</DisplayText><record><rec-number>49</rec-number><foreign-keys><key app="EN" db-

id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1437077734">49</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Morreale de Escobar, G</author><author>Obregón, M J</author><author>Escobar del Rey, F</author></authors></contributors><titles><title>Role of thyroid hormone during early brain development</title><secondary-title>European Journal of Endocrinology</secondary-title></titles><periodical><full-title>European Journal of Endocrinology</full-title></periodical><pages>U25-U37</pages><volume>151</volume><number>Suppl 3</number><dates><year>2004</year><pub-dates><date>November 1, 2004</date></pub-dates></dates><urls><related-urls><url>http://www.eje-online.org/content/151/Suppl_3/U25.abstract</url></related-urls></urls><electronic-resource-num>10.1530/eje.0.151U025</electronic-resource-num></record></Cite></EndNote>]. The EPA considered all of the recommendations from the January 2017 peer review and implemented those needed to increase the scientific rigor of the model and modeling results. These modifications include:

- Extending the model to early pregnancy;
- Incorporating biological feedback control of hormone production via TSH signaling, such that the model can describe lower levels of iodide nutrition;
- Calibrating the model and evaluating its behavior for upper and lower percentiles of the population, as well as the population median; and

- Conducting an uncertainty analysis for key parameters.

The EPA convened a second independent peer review panel in 2018 to evaluate these updates to the BBDR model. The EPA also presented several approaches to link the thyroid hormone changes in a pregnant mother predicted by the BBDR model to neurodevelopmental effects, using evidence from the epidemiological literature. The January 2018 peer review was largely supportive of the efforts described in the Draft Approaches Report, as evidenced by the following from the peer review final report:

> *Overall, the panel agreed that the EPA and its collaborators have prepared a highly innovative state-of-the-science set of quantitative tools to evaluate neurodevelopmental effects that could arise from drinking water exposure to perchlorate. While there is always room for improvement of the models, with limited additional work to address the committee's comments [in the peer-reviewed report], the current models are fit-for-purpose to determine an MCLG (External Peer Reviewers for U.S. EPA, 2018, p. 2).*

The EPA has revised its analysis of perchlorate health effects based upon the SAB and subsequent peer review recommendations. The analysis informing the derivation of the MCLG and benefits of avoided perchlorate exposure is based upon a 2-step approach to modeling the neurodevelopmental effects on offspring of pregnant women exposed to perchlorate in drinking water (see Figure 1). The approach uses a combination of the BBDR model that simulates perchlorate impacts on maternal thyroid hormones during pregnancy and the epidemiology literature that relates incremental changes in maternal thyroid hormones to neurodevelopmental outcomes in children. The following sections describe the approach in greater detail.

Figure 1. Two-Step Modeling Approach to Link Maternal Perchlorate Exposure to Measurable Adverse Neurodevelopmental Impacts in Offspring

[EMBED Visio.Drawing.15]

E. Identification of the Sensitive Population

The SAB recommended that the EPA use specific sensitive populations to develop the MCLG for perchlorate: "the fetuses of hypothyroxinemic pregnant women, and infants exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women" (SAB for the U.S. EPA, 2013, p. 19).

The EPA's proposed MCLG aims to protect the most sensitive population, the fetuses of a first trimester pregnant mother with low-iodine intake levels (i.e., 75 µg/kg/day), low fT4 levels (i.e., 10th percentile of a fT4 distribution for individuals with 75 µg/day iodine intake), and weak TSH feedback strength (i.e., TSH feedback is reduced to be approximately 60 percent less effective than for the median individual). The EPA believes that by protecting this population, the other sensitive populations (i.e., breast- and bottle-fed infants) identified by the SAB will also be protected. This conclusion is based on the EPA's analysis of predictions of the impact of perchlorate on fT4 levels from the original EPA BBDR model (which was peer reviewed in January of 2017) and an analysis of the literature on the connection between altered thyroid hormones in these life stages, and neurodevelopmental outcomes.

The EPA's original BBDR model demonstrated that perchlorate had minimal impact on the thyroid hormone levels for 30-, 60-, and 90-day formula-fed infants, even at doses as high as 20 μg/kg/day. Specifically, the model demonstrated that "the range of iodine levels in formula is sufficient to almost entirely offset the effects of perchlorate exposure at 30, 60 and 90 days" [ADDIN EN.CITE <EndNote><Cite><Author>U.S. EPA</Author><Year>2016</Year><RecNum>246</RecNum><Suffix>`; p. 73</Suffix><DisplayText>(U.S. EPA, 2016; p. 73)</DisplayText><record><rec-number>246</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1468339271">246</key></foreign-keys><ref-type name="Generic">13</ref-type><contributors><authors><author>U.S. EPA,</author></authors><secondary-authors><author>Paul Schlosser, Teresa Leavens, and Santhini Ramasamy</author></secondary-authors></contributors><titles><title>Biologically based dose response models for the effect of perchlorate on thyroid hormones in the infant, breast feeding mother, pregnant mother, and fetus: model development, revision, and preliminary dose-response analyses </title><secondary-title>Peer Review Draft</secondary-title></titles><dates><year>2016</year></dates><urls></urls></record></Cite></EndNote>]. As a result of these findings the EPA concluded that any MCLG based on the fetus of the first trimester hypothyroxinemic pregnant mother would also protect the formula-fed infant.

To determine if the same would be true for the breast-fed infant, the EPA compared the predicted percent change in fT4 experienced at given doses of perchlorate for both the breast-fed infant and the first trimester pregnant mother at varying doses of iodine intake[3] (50 to 100 µg/day). Assuming 2 or 4 µg/kg/day of perchlorate, the first trimester hypothyroxinemic pregnant mother has a greater percent change in fT4 compared to the 30 and 60 day breast-fed infant at all maternal iodine intake levels evaluated, except for the 30 day breast-fed infant of a mother consuming only 50 µg/day iodine. However, given that the original BBDR model did not have a TSH feedback loop, T4, fT4, T3 and fT3 predictions for lactating mothers with less than 75 µg/day iodine intake were considered highly uncertain because the thyroid hormone levels had fallen into the hypothyroid range.

The Agency found that there is a body of literature indicating that minor perturbations in thyroid hormone levels in the first trimester mother can adversely impact her offspring's neurodevelopment (USEPA, 2017):

> "[c]hildren exposed gestationally to maternal hypothyroxinemia (without hypothyroidism) show reduced levels of global and specific cognitive abilities, as well as increased rates of behavior problems including greater dysregulation in early infancy and attentional disorders in childhood [ADDIN EN.CITE ADDIN EN.CITE.DATA]. Notably these effects are correlated with both degree [ADDIN EN.CITE ADDIN EN.CITE.DATA] and duration [ADDIN EN.CITE

[3]Given that the current version of the BBDR model contains a TSH feedback loop and the infant models previously developed did not contain this feedback loop, this comparison is done with the feedback loop turned off.

<EndNote><Cite><Author>Pop</Author><Year>2003</Year><RecNum>25</RecNum><DisplayText>(Pop et al., 2003)</DisplayText><record><rec-number>25</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1432047641">25</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Pop, V J</author><author>Brouwers, E P</author><author>Vader, H L</author><author>Vulsma, T</author><author>van Baar, A L</author><author>de Vijlder, J J</author></authors></contributors><titles><title>Maternal hypothyroxinemia during early pregnancy and subsequent child development: a 3-year follow-up study</title><secondary-title>Clinical Endocrinology</secondary-title></titles><periodical><full-title>Clinical Endocrinology</full-title></periodical><pages>282-288</pages><volume>59</volume><section>282</section><dates><year>2003</year></dates><urls></urls></record></Cite></EndNote>] of maternal hypothyroxinemia” [ADDIN EN.CITE

<EndNote><Cite><Author>SAB</Author><Year>2013</Year><RecNum>50</RecNum><Suffix>`; p. 10</Suffix><DisplayText>(SAB, 2013; p. 10)</DisplayText><record><rec-number>50</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29"

timestamp="1437138201">50</key></foreign-keys><ref-type name="Government Document">46</ref-type><contributors><authors><author>SAB,</author></authors><secondary-authors><author>U.S. Environmental Protection Agency,</author></secondary-authors></contributors><titles><title>Advice on approaches to derive a maximum contaminant level goal for perchlorate. EPA-SAB-13-004</title></titles><dates><year>2013</year></dates><pub-location>Washington, DC</pub-location><urls></urls></record></Cite></EndNote>].

The EPA did not find analogous evidence linking minor perturbations in thyroid hormones during infancy to adverse neurodevelopmental outcomes in infants. As stated by the California Environmental Protection Agency (CalEPA) in their assessment of a public health goal for perchlorate, “the fetus is highly sensitive to any changes in thyroid hormone levels during pregnancy. It is unknown whether the neonate is similarly sensitive” [ADDIN EN.CITE <EndNote><Cite ExcludeAuth="1"><Author>California Environmental Protection Agency (CalEPA)</Author><Year>2015</Year><RecNum>62</RecNum><Prefix>CalEPA`, </Prefix><Suffix>`; p. 90</Suffix><DisplayText>(CalEPA, 2015; p. 90)</DisplayText><record><rec-number>62</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1437413166">62</key></foreign-keys><ref-type name="Government Document">46</ref-type><contributors><authors><author>California Environmental Protection Agency

(CalEPA),</author></authors><secondary-authors><author>Office of Environmental Health Hazard Assessment</author></secondary-authors></contributors><titles><title>Public health goal for perchlorate in drinking water</title></titles><dates><year>2015</year></dates><urls></urls></record></Cite></EndNote>]. Two studies evaluated both the impact of maternal hypothyroxinemia and infant fT4 levels on subsequent neurodevelopmental outcomes. [HYPERLINK \l "_ENREF_9" \o "Costeira, 2011 #7"] found that children born to mothers with low fT4 in the first trimester had increased odds of mild-to-severe delays in psychomotor development compared to children born to mothers with normal fT4 levels. However, the authors found that neonatal thyroid status (measured on day 3 after birth) did not influence development. Additionally, [HYPERLINK \l "_ENREF_17" \o "Henrichs, 2010 #928"] found in their evaluation that although maternal hypothyroxinemia was associated with language delay and nonverbal cognitive delay, the neonatal thyroid status (thyroid hormones measured in cord blood) did not explain the relationship between maternal hypothyroxinemia, early pregnancy, and children's cognitive impairment.

The SAB pointed to two lines of evidence supporting their suggestion of the infant as a sensitive population to perchlorate: preterm infants that experience transient hypothyroxinemia of prematurity (THOP) and infants that experience congenital hypothyroidism. Thus, sufficient thyroid hormone levels in infancy are necessary for the infant brain to develop properly. However, the best evidence linking perturbations in thyroid hormone levels to disrupted neurodevelopment for infants are in individuals with significant thyroid deficiencies manifesting as clinical conditions (e.g., THOP and congenital hypothyroidism). It is unclear and unknown if minor perturbations in thyroid hormones in infants, such as those that could be caused by environmental levels of perchlorate, would result in adverse neurodevelopmental outcomes similar to those seen in the literature for the offspring of first trimester pregnant mothers with hypothyroxinemia. Given the lack of evidence demonstrating minor perturbations in infant fT4 levels as being associated with neurodevelopmental outcomes, the EPA has concluded that it is appropriate to derive the perchlorate MCLG to protect the first trimester fetus of a pregnant mother with low-iodine intake. EPA concludes that an MCLG calculated to offer a margin of protection against adverse health effects to these fetuses targets the most sensitive population and will be protective of other potentially sensitive life stages as well.

F. BBDR Model Specification for the Sensitive Population

The BBDR model used to develop the proposed MCLG has two main components:

- a pharmacokinetic model for perchlorate and iodide, which describes chemical absorption, distribution, metabolism, and excretion of perchlorate and iodide; and
- a pharmacodynamic model, which describes the joint effect of varying perchlorate and iodide blood concentrations on thyroidal uptake of iodide and subsequent production of thyroid hormones, including fT4.

The pharmacokinetic model component contains a physiological description of a human mother and fetus during pregnancy (e.g., organ volumes, blood flows) and chemical-specific information (e.g., partition coefficients, volume of distribution, rate constants for transport, metabolism, and elimination) that enable a prediction of perchlorate and iodide internal concentration at the critical target (i.e., thyroidal sodium-iodide symporter of the mother) in association with a particular exposure scenario (route of exposure, age, dose level). This component of the model is similar to other PBPK models and for perchlorate is simplified by the absence of metabolism.

The pharmacodynamic component of the model uses this internal concentration to simulate how the chemical will act within a known mechanism of action to perturb host systems and lead to a toxic effect.

Thus, the BBDR model predicts serum thyroid hormone levels in the mother at specific gestation weeks, given specific levels of iodine intake, the TSH feedback loop strength, and perchlorate doses. As noted above, the EPA chose to model a sensitive individual (an adult woman with low iodine through the first trimester of pregnancy) to derive an MCLG to protect the target population with an adequate margin of safety.

The BBDR model simulates perchlorate's impact on thyroid hormones at each gestational week from conception to week 16. To derive the MCLG, the EPA selected outputs for gestational week 13 to correspond with the thyroid hormone data reported in Korevaar et al. (2016), which is the basis for the Agency's quantitative relationship between maternal thyroid hormone levels and neurodevelopmental impacts.

Individuals with low iodine intake have increased sensitivity to perchlorate's impact on thyroid hormone levels as the functional iodide reserve of the hypothalamic-pituitary-thyroid

(HPT) system is limited [ADDIN EN.CITE <EndNote><Cite><Author>Leung</Author><Year>2010</Year><RecNum>1160</RecNum><DisplayText>(Leung, Pearce, & Braverman, 2010)</DisplayText><record><rec-number>1160</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1495206437">1160</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Leung, A. M.</author><author>Pearce,</author><author>Braverman</author></authors></contributors><titles><title>Perchlorate, iodine and the thyroid</title><secondary-title>Best Practice and Research: Clinical Endocrinology and Metabolism</secondary-title><alt-title>Best Pract Res Clin Endocrinol Metab</alt-title><short-title>Best Practice and Research: Clinical Endocrinology and Metabolism</short-title></titles><alt-periodical><full-title>Best Pract Res Clin Endocrinol Metab</full-title></alt-periodical><pages>133-141</pages><volume>24</volume><number>1</number><dates><year>2010</year></dates><isbn>ISSN 1521-690X
EISSN 1532-1908</isbn><label>755955</label><work-type>Review</work-type><urls><related-urls><url>http://dx.doi.org/10.1016/j.beem.2009.08.009</url></related-urls></urls><electronic-resource-num>10.1016/j.beem.2009.08.009</electronic-resource-num><language>English</language></record></Cite></EndNote>]. The EPA selected an iodine intake level of 75 μg/day to simulate an individual with low-iodine intake. This value represents an intake between the 15th and 20th percentile of the population distribution of estimated iodine intake from the National Health and Nutrition Examination Survey (NHANES). The EPA considered using a lower iodine intake level of 50 µg/day, which represents approximately the 5th percentile of the NHANES distribution. At 50 µg/day of iodine intake, however, the BBDR model predicts TSH levels that would be elevated to within the clinically hypothyroid range before exposure to any perchlorate[4] (TSH ranges between 4.51 and 5.41 milli-

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[4] For the purposes of this analysis, the EPA evaluated the American Thyroid Association's (ATA's) 2017 recommendations for defining hypothyroidism [ADDIN EN.CITE <EndNote><Cite><Author>Alexander</Author><Year>2017</Year><RecNum>1895</RecNum><DisplayText>(Alexander et al., 2017)</DisplayText><record><rec-number>1895</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1497970921">1895</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Alexander, E. K.</author><author>Pearce, E. N.</author><author>Brent, G. A.</author><author>Brown, R. S.</author><author>Chen, H.</author><author>Dosiou, C., </author><author>Sullivan, S.</author></authors></contributors><titles><title>2017 Guidelines of the American Thyroid Association for the diagnosis and management of thyroid disease during pregnancy and the postpartum</title><secondary-title>Thyroid</secondary-title></titles><periodical><full-title>Thyroid</full-title></periodical><pages>315-389</pages><volume>27</volume><number>3</number><dates><year>2017</year></dates><urls></urls></record></Cite></EndNote>]. Specifically the ATA recommends "in the pregnancy setting, maternal hypothyroidism is defined as a TSH concentration elevated beyond the upper limit of the pregnancy-specific reference range" [ADDIN EN.CITE <EndNote><Cite><Author>Alexander</Author><Year>2017</Year><RecNum>1895</RecNum><Pages>332</Pages><DisplayText>(Alexander et al., 2017, p. 332)</DisplayText><record><rec-number>1895</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1497970921">1895</key></foreign-keys><ref-type name="Journal Article">17</ref-

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type><contributors><authors><author>Alexander, E. K.</author><author>Pearce, E. N.</author><author>Brent, G. A.</author><author>Brown, R. S.</author><author>Chen, H.</author><author>Dosiou, C., </author><author>Sullivan, S.</author></authors></contributors><titles><title>2017 Guidelines of the American Thyroid Association for the diagnosis and management of thyroid disease during pregnancy and the postpartum</title><secondary-title>Thyroid</secondary-title></titles><periodical><full-title>Thyroid</full-title></periodical><pages>315-389</pages><volume>27</volume><number>3</number><dates><year>2017</year></dates><urls></urls></record></Cite></EndNote>]. ATA goes on to state, in the absence of population- and trimester-specific reference ranges defined by a provider's institute or laboratory, that the TSH reference ranges should be obtained from similar patient populations. From their recommended studies with trimester-specific data on a U.S. population, Lambert-Meserlian et al. [ADDIN EN.CITE <EndNote><Cite ExcludeAuth="1"><Author>Lambert-Messerlian</Author><Year>2008</Year><RecNum>100</RecNum><DisplayText>(2008)</DisplayText><record><rec-number>100</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1443808320">100</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Lambert-Messerlian, Geralyn</author><author>McClain, Monica</author><author>Haddow, James E</author><author>Palomaki, Glenn E</author><author>Canick, Jacob A</author><author>Cleary-Goldman, Jane</author><author>Malone, Fergal D</author><author>Porter, T Flint</author><author>Nyberg, David A</author><author>Bernstein, Peter</author></authors></contributors><titles><title>First-and second-trimester thyroid hormone reference data in pregnant women: a FaSTER (First-and Second-Trimester Evaluation of Risk for aneuploidy) Research Consortium study</title><secondary-title>American journal of obstetrics and gynecology</secondary-title></titles><periodical><full-title>American journal of obstetrics and gynecology</full-title></periodical><pages>62-e1</pages><volume>199</volume><number>1</number><dates><year>2008</year></dates><publisher>Elsevier</publisher><isbn>0002-9378</isbn><urls></urls></record></Cite></EndNote>] is the largest U.S.-based population with a reference range upper bound of 3.37 mIU/L for the first trimester (and 3.35 mIU/L for the second trimester). Therefore, these values were used to compare to BBDR output TSH values in the first trimester (or second trimester in cases of gestational weeks 15 and 16) to determine the presence of hypothyroidism.

international units per liter (mIU/L) at zero dose of perchlorate when evaluating gestational weeks 12 or 13). In contrast, at 75 μg/day iodine, the BBDR modeled concentrations of serum fT4 and TSH are significantly reduced from the population median but are still within the euthyroid range. Thus, the intake of 75 μg/day is a better approximation of the sensitive population – the offspring of pregnant women who have low fT4.

TSH increases in response to decreases in T4 have been captured in numerous studies that document the relationship between these hormones[ADDIN EN.CITE ADDIN EN.CITE.DATA]. The BBDR model achieves this feedback regulation by adjusting a set of three parameters: the number of sodium-iodide symporter sites, the T4 synthesis rate, and the T3 synthesis rate. The BBDR model allowed for variability in the strength of the TSH feedback by varying these parameters with a variable called "pTSH." For the MCLG analysis, the EPA used a pTSH value of 0.398, which is the ratio of a median value for TSH from NHANES (non-pregnant women) to the 97.5 percentile value from NHANES (non-pregnant women). This value represents an assumption that sensitive individuals with high TSH and average fT4 levels exist, and this is because the stimulus strength of TSH is proportionally weaker. The EPA chose to use a low TSH feedback coefficient to ensure the MCLG is protective of the sensitive population.

Example output from the BBDR model for gestational week 13 and a low TSH feedback coefficient is presented in [REF _Ref517525852 \h * MERGEFORMAT].

Table III-[SEQ Table * ARABIC]. Summary of BBDR Model Results for fT4 for Gestational Week 13 at 75 μg/day Iodine Intake at pTSH[a] = 0.398 []

Perchlorate Dose (μg/kg/day)	Percentile fT4 (pmol/L)[b] (% decrease from 0 dose)			
	2.5th	5th	10th	50th
0	5.57	6.09	6.70	8.84
1	5.50 (-1.26%)	6.02 (-1.15%)	6.63 (-1.04%)	8.77 (-0.79%)
2	5.43 (-2.45%)	5.96 (-2.24%)	6.56 (-2.04%)	8.71 (-1.54%)
3	5.37 (-3.59%)	5.96 (-3.28%)	6.50 (-2.98%)	8.64 (-2.26%)
4	5.31 (-4.68%)	5.83 (-4.28%)	6.44 (-3.89%)	8.58 (-2.95%)
5	5.25 (-5.73%)	5.77 (-5.23%)	6.38 (-4.76%)	8.52 (-3.60%)
6	5.19 (-6.73%)	5.72 (-6.14%)	6.33 (-5.59%)	8.47 (-4.23%)
7	5.14 (-7.69%)	5.66 (-7.02%)	6.27 (-6.39%)	8.41 (-4.84%)

[a] See U.S. EPA, (2018d) for additional information on pTSH.
[b] The 50th percentile is direct output from the BBDR model, and additional percentiles are estimated by assuming a normal distribution with a SD of 1.67

When modeling changes in fT4, the baseline level of fT4 affects the magnitude of changes seen as a result of perchlorate exposure. Therefore, to predict the impact of perchlorate exposure on the population distribution of fT4, the EPA estimated a distribution for fT4 plasma concentrations around the median modeled values based on fT4 data from studies that were used to calibrate the BBDR model (C. Li et al., 2014; Männistö et al., 2011; Zhang et al., 2016). The EPA assumed the variation around predicted fT4 concentrations would likely be close to normal after accounting for perchlorate and iodine intake, and thus estimated a combined standard deviation (SD) using the distributional information from each of the studies (C. Li et al., 2014; Männistö et al., 2011; Zhang et al., 2016). The EPA then used the estimated combined SD to predict a distribution of fT4 around the median fT4 estimated by the BBDR model. From this distribution, the EPA chose to use the 10th percentile of baseline fT4 to conduct its analyses to account for variability in thyroid hormones in the population and to assure a dose of perchlorate is selected that will protect the most sensitive population from adverse effects[5].

G. Epidemiological Literature

The SAB recommended that EPA integrate BBDR model results with data on neurodevelopmental outcomes from epidemiological studies. There is substantial epidemiological evidence that early pregnancy hypothyroxinemia is a risk factor for a variety of adverse neurodevelopmental outcomes, including those related to both cognition and behavior (Costeira et al., 2011; Finken, van Eijsden, Loomans, Vrijkotte, & Rotteveel, 2013; Ghassabian et al., 2014; Gyllenberg et al., 2016; Henrichs et al., 2010; Júlvez et al., 2013; Kooistra, Crawford, van Baar, Brouwers, & Pop, 2006; Korevaar et al., 2016; Y. Li et al., 2010; Oostenbroek et al., 2017; Päkkilä et al., 2015; Pop et al., 2003, 1999; Román et al., 2013; van Mil et al., 2012). This conclusion, that maternal hypothyroxinemia is associated with offspring neurodevelopment, is also supported by three meta-analyses (including one full systematic review), all of which conclude maternal hypothyroxinemia is associated with increased risk of

[5] For a discussion on the details of the BBDR model, including uncertainties associated with the model the reader is directed to section 3.5 of the MCLG Approaches Report.

cognitive delay, intellectual impairment, or lower scores on performance tests when considering the entire body of evidence on this topic [ADDIN EN.CITE ADDIN EN.CITE.DATA]. Additionally, the American Thyroid Association also concludes that "overall, available evidence appears to show an association between hypothyroxinemia and cognitive development of the offspring" (Alexander et al., 2017, p. 337).

As multiple sources (e.g., the American Thyroid Association, several meta-analyses and one full systematic review) concluded that maternal hypothyroxinemia is associated with adverse neurodevelopmental outcomes, and as the SAB recommended that the EPA "consider available data on potential adverse health effects (neurodevelopmental outcomes) due to thyroid hormone level perturbations regardless of the cause of those perturbations" (p. 25), the EPA did not conduct a full systematic review and weight of evidence evaluation between maternal thyroid hormones and neurodevelopmental outcomes. Instead, a methodologic approach to reviewing the literature was conducted to evaluate the body of literature on this topic. This approach assisted in extrapolating the relationship modeled by the BBDR model to neurodevelopmental outcomes by concentrating on studies that allowed for evaluation of incremental changes in fT4 as they relate to incremental changes in neurodevelopmental outcomes. Ultimately, the EPA developed a dose-response function that predicts incremental changes in a neurodevelopmental endpoint based on a given change in thyroid hormone concentration (fT4), which could be linked to a given dose of perchlorate using the BBDR model.

To develop the dose-response function, the EPA screened the available 71 epidemiological studies, which potentially pertained to altered maternal thyroid hormone levels and offspring neurodevelopment to identify candidates based on the following criteria:

- Compatible with the sensitive life stages identified by the NRC and SAB;
- Continuous measure of thyroid hormone values (versus categorical values);
- Low risk of bias based on analysis using the National Toxicology Program's Office of Health Assessment and Translation (OHAT) Risk of Bias (ROB) tool score; and
- Access to underlying data.

Using these screening steps, the EPA categorized all 71 studies into three groups. One group consisted of studies that were not compatible[6] with extending the BBDR model (40 papers). Another group consisted of papers that were relevant to the pertinent life stages but did not have data from which a dose-response analysis could be conducted (15 studies). This includes studies that compared differences between groups, for example studies of offspring of mothers with hypothyroxinemia versus offspring of mothers without hypothyroxinemia.

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[6] For example, if the study evaluated the impact of only neonatal thyroid hormones (i.e., at a potentially sensitive life stage), it cannot be used because the BBDR model is specific to early pregnancy. Further, if the study evaluates a population with an existing disease (i.e., hypothyroidism) that may have a different response to perchlorate compared to the euthyroid population, it was not considered compatible with BBDR model results. Additionally, if the study does not include information on T4 or fT4, it does not assist in understanding the implications of the BBDR modeling results. Another reason for exclusion at this stage include that the study does not have a population with an exposure window (i.e., when the thyroid hormone measurements are taken) that overlaps with the outputs for the BBDR model. Specifically, the study should evaluate thyroid hormone levels in pregnant mothers between conception and gestational week 16. The neurodevelopmental outcomes could be measured at any life stage.

Consequently, these studies may have provided insight into the maternal thyroid hormone and offspring neurodevelopment relationship but did not have enough information to develop a continuous dose-response function. The last group of papers had data that may inform a dose-response function (16 studies). This last group of papers included publications that may have had categorical analyses but also presented data that assessed fT4 as a continuous variable and the outcome of interest. In most instances, the continuous fT4 variable encompassed the full range for fT4 and not just the hypothyroxinemic range. After excluding one paper due to a high risk of bias (Kastakina et al., 2006) 15 papers remained that potentially had dose-response data between a continuous measure of fT4 and various neurodevelopmental outcomes describing cognition, behavior, and other outcomes such as schizophrenia.

From these 15 papers five were selected for dose response assessment - four related to cognition [ADDIN EN.CITE ADDIN EN.CITE.DATA] and one related to behavior [ADDIN EN.CITE
<EndNote><Cite><Author>Endendijk</Author><Year>2017</Year><RecNum>1915</RecNum><DisplayText>(Endendijk, Wijnen, Pop, & van Baar, 2017)</DisplayText><record><rec-number>1915</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29" timestamp="1503500102">1915</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Endendijk, J.J.</author><author>Wijnen, H.A.</author><author>Pop, V.J.</author><author>van Baar,

A.L.</author></authors></contributors><titles><title>Maternal thyroid hormone trajectories during pregnancy and child behavioral problems</title><secondary-title>Horm Behav</secondary-title></titles><periodical><full-title>Horm Behav</full-title></periodical><pages>84-92</pages><volume>94</volume><dates><year>2017</year></dates><urls></urls></record></Cite></EndNote>]. The other ten papers were excluded for a variety of reasons including updated analyses being presented in a different paper for which dose-response analysis was being conducted, lack of all the data needed to complete a dose-response assessment (e.g., dose-response results were presented as "per standard deviation of fT4" but the standard deviation needed to fully interpret the results for a continuous function was not presented in the paper, statistical methods presented in the paper were insufficient to allow for the derivation of a concentration response function), or a lack of a relationship between maternal fT4 as a continuous variable and the outcome of interest evaluated in the paper. For example, Noten et al. (2015) found a relationship between maternal hypothyroxinemia and offspring arithmetic test performance. However, maternal fT4 as a continuous variable across the entire fT4 range was not associated with arithmetic test performance. Given this null finding, as well as the lack of published literature evaluating maternal fT4 as a continuous variable and arithmetic test performance, it would be difficult for the Agency to justify setting an MCLG based on changes in this endpoint.

For each study deemed appropriate for dose-response modeling, a relationship between maternal thyroid hormone levels (specifically fT4) and offspring neurodevelopment was derived (see USEPA, 2018d). These relationships were either presented in the paper or derived by the EPA through either the digitization of figures or through re-analysis of data provided by the study authors. The EPA used the upper effect estimate (the upper bound of the 95th percent confidence interval) from each study to determine the dose of perchlorate associated with a given change in fT4. Table III-2 provides a summary of the changes in fT4 needed to produce a 1 ~~percent to~~ , 2, and 3 percent decrease in the neurodevelopmental effect and corresponding perchlorate doses. These results provide a perspective on the potential impacts of perchlorate on maternal fT4 (as predicted by the BBDR model) and subsequent neurodevelopmental impacts (as predicted by the epidemiologic literature[7]).

Table III-2. Predicted Dose of Perchlorate per 1 ~~Percent to~~, 2, and 3 Percent Decrease[a] in Neurodevelopmental Measure for the Population of Low-Iodine Intake Individuals Based on Upper Effect Estimates at the 10th Percentile fT4 Level[b]

Study	Endpoint	Dose-Response Function	β (95% CI)	ΔfT4 in pmol/L Associated with a 1% to 3% Decrease in Endpoint (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 µg/day)[a, b, c, d]			Dose of Perchlorate per 1% to 3% Decrease in Endpoint (µg/kg/day)[a, b, c, d]		
				1%	2%	3%	1%	2%	3%
Korevaar et al. (2016) Quadratic	IQ	$\Delta IQ = (\beta_1 \times lnfT4_2 + \beta_2 \times ln(fT4_2)^2) -$	β1 = 33.8 (9.8, 57.8) β2 = -6.2 (-10.6, -1.9)	-0.13 (1.9%)	~~to~~ -0.25 (~~1.9% to~~ 3.8%)	-0.38 (5.7%)	1.9 ~~to 3.9~~	3.9	6.1

[7] For a more complete description of all the studies evaluated the reader is directed to Sections 5 and 6 of the Approaches report. For a discussion on the uncertainties related to the approach the reader is directed specifically to section 6.5.

Study	Endpoint	Dose-Response Function	β (95% CI)	ΔfT4 in pmol/L Associated with a 1% to 3% Decrease in Endpoint (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 µg/day)[a, c]			Dose of Perchlorate per 1% to 3% Decrease in Endpoint (µg/kg/day)[a, c]		
				1%	2%	3%	1%	2%	3%
		$(\beta_1 \times lnfT4_1 + \beta_2 \times ln(fT4_1)^2)$							
Korevaar et al. (2016) EPA independent analysis	IQ	$\Delta IQ = (\beta_1 \times \ln(fT4_2)) - (\beta_1 \times \ln(fT4_1))$	17.26 (3.77, 30.75)	-0.21 (3.1%)	~~to~~ -0.41 ~~(3.1% to~~ (6.2%)	-0.61 (9.2%)	3.1 ~~to 6.7~~	6.7	10.8
Pop et al. (2003)	MDI	$\Delta MDI = \beta \times \Delta fT4$	6.3 (1.92, 10.6)	-0.09 ~~to -0.19~~ (1.0~~% to 2.8~~%)	~~1.3 to~~ -0.19 (2.8%)	-0.28 (4.2%)	1.3	2.8	4.3
Pop et al. (2003)	PDI	$\Delta PDI = \beta \times \Delta fT4$	8.4 (4.0, 12.8)	-0.08 ~~to -0.16~~ (0.9~~% to 2.4~~%)	-0.16 (2.4%)	-0.23 (3.5%)	1.1 ~~to 2.3~~	2.3	3.5
Pop et al. (1999)	PDI	$\Delta PDI = \beta \times \Delta fT4$	8.5 (0.01, 17.0)	-0.06 ~~to -0.12~~ (0.6~~% to 1.8~~%)	-0.~~8 to~~ 12 (1.~~7~~8%)	-0.18 (2.6%)	0.8	1.7	2.6
Endendijk et al. (2017)	Anxiety/ depression score	$\Delta AD = \left(\frac{1}{\beta * fT4_2}\right) - \left(\frac{1}{\beta * fT4_1}\right)$	0.12 (0.11, 0.13)	-0.03 (0.45%)	~~to~~ -0.08 ~~(0.45% to~~ (1.2%)	-0.12 (1.9%)	0.4 ~~to 1.1~~	1.1	1.8
Finken et al. (2013)	SD of reaction time	ΔSD Reaction Time (ms) = β × Δ fT4	-4.9 (-9.5, -0.2)	-0.28 (4.2%)	~~-0.28 to~~ -0.57 ~~(4.2% to~~ (8.5%)	-0.85[d] (12.7%)	4.4 ~~to 9.8~~	9.8	16.5[d]

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Study	Endpoint	Dose-Response Function	β (95% CI)	ΔfT4 in pmol/L Associated with a 1% to 23% Decrease in Endpoint (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 μg/day)[a, c, d]			Dose of Perchlorate per 1% to 23% Decrease in Endpoint (μg/kg/day)[a, c, d]		
				1%	2%	3%	1%	2%	3%

[a] The analyses for IQ, Mental Development Index (MDI), and Psychomotor Development Index (PDI) are based on a 1%%, 2%, or 23% change from the standardized mean for each test (i.e., 100 points), which equates to a 1, 2, or 23 point change, respectively. The analyses for anxiety/depression score and SD of reaction time are based on a 1%%, 2%, or 23% change from the study mean of each measure, which for anxiety/depression is 0.01 ~~and~~, 0.02, or 0.03 points, respectively, and for reaction time is 2.7 ~~and~~, 5.4, and 8.1 milliseconds (study mean SD of reaction time = 270 ms), respectively.

[b] This is based on the regression analysis for the range of fT4 data within each study using the upper beta estimates from the 95% CI. These results are for the low-iodide intake population of 75 μg/day. In all functions, fT4 is in units of pmol/L.

[c] The BBDR model with a pTSH of 0.398 was used for these analyses.

~~[d] Ranges show results from a 1% change in the endpoint from its mean value to a 2% change in the endpoint from its mean.~~ [d] The value which results in a 3% change in the standard deviation of reaction time falls between 16 and 17 μg/kg/day. Because data was not available on the changes of fT4 at doses between 16 and 17 μg/kg/day perchlorate, the EPA took the midpoint of the range of values for the change in fT4 at 16 and 17 μg/kg//day and assumed the dose of perchlorate associated with this change was the midpoint between 16 and 17 μg/kg/day.

From the seven analyses presented, the EPA chose an independent analysis of the Korevaar et al. (2016) data (comprising 3,600 useable mother/child data pairs) as the basis for calculating the point of departure (POD) for the MCLG. The reason for this selection is that an adverse health impact function can be derived for the sensitive population of interest, adjusting for the appropriate set of confounders, with a readily interpretable endpoint – intelligence quotient (IQ); the other studies do not provide one or more of these features (USEPA, 2018d). The EPA selected an independent analysis of the Korevaar data instead of the original analysis to incorporate analytical changes suggested by the 2018 peer-review panel (External Peer Reviewers for USEPA, 2018). The revised analysis controls for a more focused set of confounders (e.g., previously included variables such as infant gender, maternal parity, birthweight, mother's BMI, and gestational age at blood draw that are not related to both the exposure and the outcome were excluded), thus decreasing the chances of overfitting the estimation of the association between maternal fT4 and child IQ[8].

Intelligence is often assessed by tests that measure intelligence quotient (IQ). There are several different tests that are widely used to measure IQ, including the Stanford-Binet and the Wechsler Intelligence Scale for Children (WISC) (Sternberg et al., 2001). Each of these tests is intended to assess a child's global functioning and uses a numerical IQ point scale (Beres et al., 2000). IQ scores are standardized by age and sex group with a mean score of 100 points and a standard deviation of 15 (Beres et al., 2000). Although the specific tasks differ by test, all IQ tests contain a number of tasks to assess diverse skills (Sternberg et al., 2001). For example, the WISC test evaluates full-scale IQ using a combination of verbal and performance scales (verbal IQ and performance IQ may also be assessed separately) (Beres et al., 2000). The verbal scale includes tasks such as arithmetic, vocabulary, and comprehension, while the performance scale includes tasks such as picture completion, block design, and object assembly (Beres et al., 2000). The WISC was standardized using a sample of 2200 U.S. children aged 6 to 16 years old (Seashore et al., 1950). It has been well validated and has demonstrated high reliability, with a reliability coefficient of 0.96 observed across age groups (Beres et al., 2000).

IQ tests have proved to be useful for several purposes. IQ scores have shown associations with both educational achievement and attainment, though observed correlations vary widely. In

[8] A more complete description of the EPA independent analysis of the Korevaar et al. (2016) data can be found in Section 6.3.2 of the Approaches report

a review of the literature, Sternberg et al. (2001) suggest that IQ scores explain approximately 25% of the variance in academic achievement. Evidence also suggests that IQ is linked to career outcomes and job performance, with observed correlations ranging from approximately 0.2 to 0.6 (Sternberg et al., 2001). In addition, IQ scores can help diagnose disorders such as mental retardation and to identify children for placement into specialized learning programs (Beres et al., 2000). For example, one criterion for the diagnosis of mild mental retardation in the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) is an IQ score between 50-55 and 70 (American Psychological Association, 2000).

Despite the clinical use of IQ cutoffs, questions remain as to what magnitude in IQ change represents a meaningful difference. Researchers have suggested that, while an IQ point change of around one to three points may not be significant on an individual level, small changes in IQ become important when considered on the population level. For example, Bellinger (2004) argues that although a one-point change in IQ is within the standard error[9] of an individual measurement and would not be regarded as clinical disease or cause affected individuals to seek medical care, it is still highly significant on a population basis. This is because a small shift in the population distribution results in potentially large differences in the number of children in the

[9] The standard error of measurement for an individual test varies depending on factors such as the choice of IQ test and age at test administration. For example, the standard error for a 9 year old in the third edition of the WISC (WISC-III) is 3.35 (Bellinger, 2004).

two tails of the IQ distribution. Rogan and Ware (2003) add that relatively small changes in the mean IQ of a large number of children will dramatically increase the proportion of the population below any fixed level of concern such as an IQ of 80 and decrease the proportion above any 'gifted' level, such as 120. Nation and Gleaves (2001) argue that, assuming there is no measurement error, the standard error on a single IQ test does not matter, since errors on individual tests will be in both directions and any differences between groups will be measurable on a population basis. Carlisle et al. (2009) identified a one IQ point decrement as a *de minimus* change in IQ based on this prior literature.

To select a perchlorate dose POD, the EPA selected the percent change in population IQ relating to no known or anticipated adverse effects. The EPA often uses a percentage change value in noncancer risk assessment. When assessing toxicological data, 5 percent or 10 percent, or a 0.5 to 1 standard deviation change from the mean is often used (U.S. EPA, 2012). A smaller response to inform a POD is justified and has been used when using epidemiological literature. Specifically, "[a] BMR of 1% has typically been used for quantal human data from epidemiology studies" (p. 21, U.S. EPA, 2012). Given that IQ is standardized to have a mean of 100, a 2-point decrease would be equivalent to a 2 percent decrease from the standardized mean IQ.

~~Additionally, the EPA has used a specific incremental change in child IQ (e.g., 1 to 2 points IQ decrement) in considering revisions to the primary National Ambient Air Quality Standard (NAAQS) for lead (73 FR 66964). Given that IQ is standardized to have a mean of 100,~~

~~a 1 to 2 point decrease would be equivalent to a 1 or 2 percent decrease from the standardized mean IQ.~~

For the specific context of perchlorate, the EPA evaluated avoiding ~~both a 1 percent decrease and a 2 percent decrease in IQ as the basis for an MCLG.~~ a 1 percent decrease, a 2 percent decrease, and a 3 percent decrease in population IQ as the basis for an MCLG. This approach was developed specifically for proposing a National Primary Drinking Water Regulation under the SDWA for perchlorate, utilizing the available literature. EPA has evaluated alternatives for deriving a perchlorate MCLG because of the uncertainty regarding the precise decrement in population IQ that represents an adverse impact. By selecting this approach, the EPA is not establishing a precedent for future Agency actions on other contaminants, since this approach might not be appropriate for conducting risks assessments or informing Agency policy for other contaminants and associated health effects. The EPA selected this approach for perchlorate to implement the recommendations provided by the Science and Advisory Board for developing a perchlorate MCLG. The EPA selected IQ decrements because this was the endpoint evaluated in the Korevaar et al. (2016) study. The EPA determined that the Korevaar study was the most rigorous analysis that examined the relationship between decreased thyroid hormones and neurodevelopmental effects. Applying these response rates to the results from the reanalysis of Korevaar et al. (2016), results in a POD dose of 3.1 µg/kg/day for a 1 percent decrease in the population's IQ, ~~and~~ a POD dose of 6.7 µg/kg/day for a 2 percent decrease in ~~IQ~~ the population's IQ, and a POD dose of 10.8 µg/kg/day for a 3 percent decrease in the population's IQ. These

PODs associated with a 1, 2 or ~~2~~3 percent decrease from the standardized mean IQ are calculated for the most sensitive population ~~defined as~~. Specifically, the assessment is aimed at protecting the fetuses of mothers ~~at the low end of the distribution of fT4~~ with ~~a low~~ fT4 at the 10th percentile of a population with iodine intake of 75 µg/day and a ~~muted~~ TSH feedback ~~response. As such,~~ loop that is less than 60% as effective as individuals with median TSH feedback loop efficacy. That is, the analysis is designed to protect the population of fetuses of mothers with suboptimal thyroid functioning. For these reasons, and for the methodological reasons described previously, EPA believes these PODs are likely protective and should not be considered predictive.

H. Translate PODs to RfDs

When deriving an RfD the application of uncertainty/variability factors needs to be evaluated to account for heterogeneity of effect in the target population and data gaps (USEPA, 2002). As presented in *A Review of the RfD & RfC Processes* (USEPA, 2002) the EPA considers the following uncertainty factors: inter-individual variability, interspecies uncertainty, extrapolating from subchronic to chronic exposure, extrapolating from a lowest-observed adverse effect level (LOAEL) rather than from a NOAEL, and an incomplete database. The EPA has considered each of these factors in deriving an RfD to inform an MCLG for perchlorate:

- Variation and uncertainty in the relationship between exposure and response among the members of the human population (i.e., inter-individual variability; uncertainty factor, within-human variability, UF_H). For this analysis a UF of 3 is used. The approach taken to derive the RfD attempts to address some of the variability between the general population and the sensitive population. Specifically, the EPA was able to modify the strength of the TSH feedback loop and iodine intake levels in the BBDR model and concentrate on the dose-response relationship between lower level (as opposed to median level) fT4 and neurodevelopmental outcomes. However, there is still uncertainty in the relationship between perchlorate exposure and subsequent neurodevelopmental outcomes[10]. There are very few toxicokinetic calibration data available for the perchlorate to thyroid hormone relationship described in the BBDR model. On the toxicodynamic side of the BBDR model, aspects such as competitive inhibition at the NIS, depletion of iodide stores under different iodine intake levels and physiological states, and the ability of the TSH feedback loop to compensate for perturbations in thyroid function each have their own uncertain features. There are also uncertainties linking maternal fT4 levels to offspring IQ. These uncertainties include the population for which dose-response information is available (i.e., no study is U.S.-based), a lack of study information on the iodine intake status for the population for which the dose-response information is available, uncertainties around the methods used to assess maternal fT4 measurement during pregnancy, and uncertainties related to the true distribution of fT4 for a given iodine intake. Further, as discussed in section III. C the EPA believes that

[10] For a more complete discussion on the uncertainties in the analysis the reader is directed to Sections 3.5 and 6.5 of the Approaches report.

protecting the fetus of a hypothyroxinemic woman will protect other identified sensitive life stages. However, there is some uncertainty due to the lack of information linking incremental changes in infant thyroid hormone levels to adverse neuorodevelopmental outcomes. Further, this analysis is assuming that protecting a first trimester fetus from alterations in maternal fT4 will protect the fetus throughout pregnancy. This is based on the strong epidemiologic evidence that shows the relationship between first trimester maternal fT4 and neurodevelopmental outcomes. ~~This is likely because before mid-gestation, the mother is the only source of thyroid hormone for the fetus~~ [ADDIN EN.CITE <EndNote><Cite><Author>Morreale de Escobar</Author><Year>2004</Year><RecNum>49</RecNum><DisplayText>(Morreale de Escobar et al., 2004)</DisplayText><record><rec-number>49</rec-number><foreign-keys><key app="EN" db-id="z9t0avxvzdfermedxe5vxfpkax2vzp0ftv29">49</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Morreale de Escobar, G</author><author>Obregon, M J</author><author>Escobar del Rey, F</author></authors></contributors><titles><title>Role of thyroid hormone during early brain development</title><secondary-title>European Journal of Endocrinology</secondary-title></titles><periodical><full-title>European Journal of Endocrinology</full-title></periodical><pages>U25-U37</pages><volume>151</volume><number>Suppl 3</number><dates><year>2004</year><pub-dates><date>November 1, 2004</date></pub-

dates></dates><urls><related-urls><url>http://www.eje-online.org/content/151/Suppl_3/U25.abstract</url></related-urls></urls><electronic-resource-num>10.1530/eje.0.151U025</electronic-resource-num></record></Cite></EndNote>]. This is likely because before mid-gestation, the mother is the only source of thyroid hormone for the fetus (Morreale de Escobar et a., 2004). Therefore, when evaluating maternal fT4 as associated with neurodevelopmental outcomes it is critical to understand the first-trimester levels. Later in gestation, when the infant begins developing its own thyroid hormones, maternal fT4 may no longer be a good surrogate for the thyroid hormone levels the fetus is receiving. Given the fetal thyroid has had little time to develop, its iodine storage is much less than that of an adult, hence there may be more sensitivity to short-term fluctuations in iodine availability and uptake that may have little impact on maternal levels. Therefore, there is some uncertainty about the impact perchlorate may have on the fetal thyroid gland, and subsequent neurodevelopmental impacts, in later trimesters of pregnancy. This should be accounted for with a UF because the immature fetal HPT axis has very limited capacity to increase output of thyroid hormones (Savin, Cvejić, Nedić, & Radosavljević, 2003; van Den Hove, Beckers, Devlieger, De Zegher, & De Nayer, 1999), so the fetal HPT may not be able to adjust output in the face of reduced maternal fT4 supply and perchlorate exposure.

- Subsequently, the Agency has opted to apply a UF of 3 to the POD. Section 4.4.5.3 (p 4-42) of the 2002 document recommends only reducing the intraspecies UF from a default of 10 "if data are sufficiently representative of the exposure/dose-response data for the most susceptible subpopulation(s)." (USEPA, 2002). A UF of 3 was selected instead of the full 10 because the EPA has specifically attempted to model the most sensitive individuals (i.e., muted TSH feedback, low fT4 values, low-iodine intake) which accounts for some of the variability within the population[11].

- Uncertainty in extrapolating animal data to humans (i.e., interspecies uncertainty) (uncertainty factor, animal-to-human, UF_A). For this analysis an UF of 1 is used because this factor is not applicable since animal studies were not used to develop the BBDR model nor were they used to relate alterations in maternal fT4 to IQ.
- Uncertainty in extrapolating data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure, UF_S). An uncertainty factor of 1 is used. Extrapolating from subchronic to chronic exposures did not occur as the BBDR model was designed to assess long-term steady-state conditions in the non-pregnant woman and week-to-week variation in pregnancy, rather than short-term (hour-to-hour or day-to-day) fluctuations.
- Uncertainty in extrapolating from a LOAEL rather than from a NOAEL (uncertainty factor, LOAEL-to-NOAEL, UF_L). A more sophisticated BBDR modeling approach, coupled with

[11] Deriving a Data-Dependent Extrapolation Factor (DDEF) was not done in this analysis. As explained in U.S. EPA, 2014 "UFs incorporate both extrapolation components that address variability (heterogeneity between species or within a population) and components that address uncertainty (i.e., lack of knowledge)…whereas DDEFs focus on variability" (p. 7, US EPA, 2014). As described above the UFs are applied based on the uncertainties in the perchlorate to thyroid hormone and thyroid hormone to neurodevelopment relationship.

extrapolation to changes in IQ using linear regression, was used to determine a POD that would not be expected to represent an adverse effect. Subsequently an uncertainty factor of 1 is used. LOAELs and NOAELs were not identified or used in this approach.

- Uncertainty factor for database deficiency to address the potential for deriving an inadequately protective RfD in the instance where the available database provides an incomplete characterization of the chemical's toxicity (database deficiency, UF_D; USEPA, 2002). An uncertainty factor of 1 is used as "[t]he mode of action of perchlorate toxicity is well understood" (SAB for the U.S. EPA, 2013, p. 2).

- The product of all the uncertainty factors (UFH) is 3 (3 x 1 x 1 x 1 x 1).

Using the POD of 6.7 µg/kg/day based on a 2 percent decrease in the population standardized mean IQ from the EPA's independent analysis of the Korevaar et al. (2016) data, the EPA can derive a RfD by incorporating the UF_H, which results in the following:

$$RfD = \frac{POD}{UF_H} = \frac{6.7}{3} = 2.23\ \frac{\mu g/kg}{day}$$

Using an alternative POD of 3.1 µg/kg/day based on a 1 percent decrease in the population standardized mean IQ from the EPA's independent analysis of the Korevaar et al. (2016) data, the EPA can derive an RfD by incorporating the UF_H. This results in the following:

$$RfD = \frac{POD}{UF_H} = \frac{3.1}{3} = 1.03\ \frac{\mu g/kg}{day}$$

Using an alternative POD of 10.8 µg/kg/day based on a 3 percent decrease in the population standardized mean IQ from the EPA's independent analysis of the Korevaar et al. (2016) data, the EPA can derive an RfD by incorporating the UF_H. This results in the following:

$$RfD = \frac{POD}{UF_H} = \frac{10.8}{3} = 3.6\ \frac{\mu g/kg}{day}$$

I. Translate RfD into an MCLG

To translate the RfD (µg/kg/day) to a concentration in drinking water (µg/L), the EPA used the following equation:

$$W\left(\frac{\mu g}{L}\right) = \frac{RfD}{DWI} \times RSC_w$$

where:

W = drinking water concentration of perchlorate in micrograms per liter (µg/L);

RfD = reference dose (1.03 µg/kg/day for a 1 percent decrease in IQ ~~or~~, 2.23 µg/kg/day for a 2 percent decrease in IQ, or 3.6 µg/kg/day for a 3 percent decrease in IQ);

DWI = bodyweight-adjusted drinking water ingestion rate (L/kg/day); and

RSC_w = relative source contribution of drinking water to overall perchlorate exposure.

The EPA selected a DWI estimate specific to women of childbearing age (i.e., non-pregnant, non-lactating, 15–44 years of age) (Table III-3). This decision is consistent with the analysis used in deriving an RSC_w (described below), which was performed using food consumption information for a population of women of childbearing age from NHANES. The EPA acknowledges there is a difference in the age range defining women of childbearing age used to develop the drinking water ingestion rate and that used to develop the RSC (20 – 44 years of age). The age range used to develop the RSC was based on the range of ages used to define women of childbearing age in developing the BBDR model. However, the EPA's Exposure Factors Handbook (USEPA, 2011b) identifies drinking water ingestion rates for women 15-44 years of age as corresponding to women of childbearing age.

The age range used for women of childbearing age in the BBDR model fits within the age range used to develop the ingestion rates provided in the Exposure Factors Handbook. Thus, the Agency believes the difference in the age ranges will have minimal impact on the resulting MCLG analysis. To calculate the MCLGs, the EPA selected the 90th percentile body-weight adjusted drinking water ingestion rate of 0.032 L/kg/day to account for variability in drinking water ingestion rates.

Table III-3. Consumers-Only Estimated Direct and Indirect Community Water Ingestion Rates from Kahn and Stralka (2008) (L/kg/day)

Female Population Categories	Sample Size	Mean	90th Percentile	95th Percentile
Pregnant	65	0.014[a]	0.033[a]	0.043[a]
Lactating	33	0.026[a]	0.054[a]	0.055[a]
Non-pregnant, non-lactating, 15 to 44 years of age	2,028	0.015	0.032	0.038

[a] The sample size does not meet minimum reporting requirements to make statistically reliable estimates as described in the *Third Report on Nutrition Monitoring in the United States*, 1994-1996 (FASEB/LSRO, 1995).

Individuals are exposed to perchlorate through ingestion of both food and drinking water (ATSDR 2008, Huber et al., 2011). In calculating the MCLGs, the EPA applies a relative source contribution (RSC) to the RfD to account for the percentage of the RfD remaining for drinking water after other sources of exposure to perchlorate have been considered. Thus, the RSC for drinking water is based on the following equation where "Food" is the perchlorate dose from food ingestion:

$$RSC = \frac{RfD-Food}{RfD} \times 100\%$$

To estimate the dose of perchlorate for women of childbearing age coming from food, the EPA implemented a data integration methodology that combined demographic variables, food consumption estimates, and perchlorate contamination estimates in food from multiple sources (USEPA, 2018e). These sources include:

- The NHANES data available from the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) including the What We Eat in America (WWEIA) 24-hour food diary data (CDC & NCHS, 2007, 2009, 2011); and
- The Food and Drug Administration's (FDA's) Total Diet Study (TDS) (U.S. Food and Drug Administration (FDA), 2015), which analyzes contaminants in more than 280 kinds of food and beverages commonly consumed by the U.S. population.

The NHANES data provided individual food consumption profiles for female participants age 20-44 (the women of childbearing age range used for the BBDR model). The EPA matched TDS perchlorate concentrations with each food consumed by a participant and calculated each participant's daily perchlorate dose (µg/kg/day) from food using the participant's body weight.

The EPA estimated each participant's perchlorate dose using both mean and 95th percentile perchlorate concentrations in food. The EPA then used these individual bodyweight-adjusted perchlorate doses from food to calculate distributions of perchlorate dose from food for the population of women age 20-44.

Table III-4 presents the mean and selected percentiles of the distribution of perchlorate dose from food for women ages 20-44, for both mean and 95th percentile perchlorate concentrations in food based on the TDS. To calculate the RSC, the EPA selected the 90th percentile dose of perchlorate from food, assuming a scenario where the food contained the 95th percentile perchlorate concentration. This corresponds to a perchlorate dose for food of 0.45 μg/kg/day. The EPA chose to use the 90th percentile bodyweight-adjusted perchlorate consumption from food using the 95th percentile TDS results to estimate the perchlorate RSC from drinking water. The EPA believes this is the most appropriate value for perchlorate consumption from food to ensure the protection of potentially highly exposed individuals. Given the range of perchlorate concentrations in food, and that food is the only other exposure source being considered in the RSC analysis, the EPA believes it is sufficiently protective to estimate the MCLG for drinking water using the 90th percentile bodyweight-adjusted perchlorate consumption based on the 95th percentile concentrations in TDS. This assures that highly exposed individuals from this most sensitive population are considered in the evaluation of whether perchlorate is found at levels of health concern.

Table III-4. Perchlorate Dose from Food (µg/kg/day) in U.S. Women Ages 20-44 using the mean and 95th Percentile TDS Results[1]

Level of Bodyweight Adjusted Perchlorate Consumption from Population Distribution	Perchlorate Dose from Food (µg/kg/day)	
	Based on Mean Concentrations of Perchlorate in Food	Based on 95th Percentile Concentrations of Perchlorate in Food
Mean	0.09 – 0.12	0.23 – 0.24
50th Percentile	0.08 – 0.10	0.17 – 0.19
90th Percentile	0.18 – 0.21	**0.45**
99th Percentile	0.33 – 0.38	1.16 – 1.17

[1] Ranges are due to various approaches for handling values <level of detection. If no range is presented all approaches resulted in the same value.
Bolded value represents the selected value

EPA used the drinking water intake and perchlorate dose from food to calculate MCLGs for the ~~two~~three RfD values. Table III-5 shows the RSC values for the ~~two~~three RfD values and the corresponding MCLGs calculated using EPA's standard equation.

Table III-5. Estimates for RSC and MCLG by RfD

RfD[a] (µg/kg/day)	RSC_W[b] (percent)	DWI (L/kg/day)	MCLG[c] (µg/L)
1.03	56%	0.032	~~18 (rounded from 18.03)~~18
2.23	80%	0.032	~~56 (rounded from 55.7)~~56
3.60	80%[d]	0.032	90

a. The RfD values corresponding to protecting the fetus of a first trimester pregnant mother with low-iodine intake levels (i.e., 75 µg/kg/day), low fT4 levels (i.e., 10th percentile of a fT4 distribution for individuals with 75 µg/day iodine intake), and weak TSH feedback strength (i.e., TSH feedback is reduced to be approximately 60 percent less effective than for the median individual) from either a 1-point IQ loss or a 2-point IQ loss, respectively.
b. The EPA calculated RSC values based on the following equation given a Food intake of 0.45 µg/kg/day:

$$RSC = \frac{RfD - Food}{RfD} \times 100\%$$

c. The EPA calculated the MCLG values based on the following equation given the respective RfD and RSC values and the DWI:

$$W\left(\frac{\mu g}{L}\right) = \frac{RfD}{DWI} \times RSC_w$$

d. The calculated RSC value using the equation in footnote b is 88 percent. However, the EPA has opted to follow previously established recommendations which employs a ceiling of 80 percent for the RSC value (USEPA 2000d).

IV. Maximum Contaminant Level Goal and ~~Alternative~~Alternatives

Section 1412(a)(3) of the SDWA requires the EPA to propose a maximum contaminant level goal (MCLG) simultaneously with the national primary drinking water regulation. The MCLG is defined in Section 1412(b)(4)(A) as "the level at which no known or anticipated adverse effects on the health of persons occurs and which allows an adequate margin of safety." The EPA is proposing an MCLG of 56 µg/L based on the rationale provided above. The derivation of the proposed MCLG is described in Section III and uses a point of departure based upon a two percent decrease in IQ. ~~The Agency also seeks comment on an alternative MCLG of 18 µg/L which is derived using the methodology described in Section III and a one percent decrease in IQ.~~The EPA selected a 2 percent decrease in IQ for the proposed perchlorate MCLG because this represents a small change in IQ, well below one standard deviation for the population. There are uncertainties (described in Section XIII) in the models used by EPA to derive the proposed and alternative MCLGs. As described in Section III, EPA has addressed these uncertainties by selecting model parameters and other factors for the derivation of the MCLG that are protective for the most sensitive life stage. EPA believes that the selection of these parameters and this point of departure assures no known or anticipated adverse effects on the health of persons and allows for an adequate margin of safety. The EPA acknowledges uncertainty with respect to the decrement of IQ that represents an adverse effect and the Agency seeks comment on the alternative MCLG values of 18 μg/L and 90 μg/L, which the EPA derived using the methodology described in Section III based on a one percent and three percent decrease in IQ, respectively.

V. Maximum Contaminant Level and ~~Alternative~~Alternatives

Under section 1412(b)(4)(B) of the SDWA, the EPA must establish a maximum contaminant level (MCL) as close to the MCLG as is feasible. The EPA evaluated available analytical methods to determine the lowest concentration at which perchlorate can be measured and evaluated the treatment technologies for perchlorate that have been examined under field conditions (USEPA 2018a, 2018c). The EPA determined that setting an MCL equal to the proposed MCLG of 56 μg/L is feasible given that the approved analytical method for perchlorate for UCMR 1 has a minimum reporting level (MRL) of 4.0 μg/L (USEPA 1999, 2000c) and that available treatment technologies can treat to concentrations well below 56 μg/L (USEPA, 2018f). Therefore, the EPA is proposing to set the MCL for perchlorate at 56 μg/L.

Because the EPA is taking comment on ~~an~~ alternative MCLG values of 18 μg/L and 90 μg/L the Agency has also evaluated the feasibility of setting an MCL at this level. The EPA determined that the proposed MCL of 56 μg/L is feasible, therefore a higher MCL alternative such as 90 μg/L is also feasible. The EPA has concluded that analytical methods are capable of measuring perchlorate at 18 µg/L and that treatment technologies have been demonstrated to achieve this level under field conditions (USEPA 2018a, 2018c). Therefore, the EPA is requesting comment on ~~an~~ alternative ~~MCL~~MCLs of 18 µg/L and 90 µg/L.

As the occurrence analysis in section VI demonstrates, there is infrequent occurrence of perchlorate at either 18 µg/L ~~or~~, 56 µg/L, or 90 µg/L. Therefore, the EPA did not evaluate alternative MCL values greater than the corresponding MCLG values. The purpose for evaluating alternative MCL values is to determine whether there is an MCL at which benefits justify the costs of setting an MCL. Given infrequent occurrence, the majority of the costs associated with establishing an NPDWR for perchlorate are for administrative and initial monitoring activities (see section XI.B), which will not be significantly affected by MCL values greater than corresponding MCLG values.

When proposing an MCL, the EPA must publish, and seek public comment on, the health risk reduction and cost analyses (HRRCA) of each alternative MCL considered (SDWA section 1412(b)(3)(C)(i)), including: the quantifiable and nonquantifiable health risk reduction benefits attributable to MCL compliance; the quantifiable and nonquantifiable health risk reduction benefits of reduced exposure to co-occurring contaminants attributable to MCL compliance; the quantifiable and nonquantifiable costs of MCL compliance; the incremental costs and benefits of each alternative MCL; the effects of the contaminant on the general population and sensitive subpopulations likely to be at greater risk of exposure; any adverse health risks posed by compliance; and other factors such as data quality and uncertainty. The EPA provides this information in section XII. The EPA must base its action on the best available, peer-reviewed science and supporting studies, taking into consideration the quality of the information and the uncertainties in the benefit-cost analysis (SDWA section 1412(b)(3)). The following sections, as well as the health effects discussion in section III document the science and studies that the EPA relied upon to develop estimates of benefits and costs and understand the impact of uncertainty on the Agency's analysis.

VI. Occurrence

The EPA conducted a national occurrence analysis of perchlorate in two types of public water supplies: community water systems (CWS) and non-transient, non-community water systems (NTNCWS). The EPA developed estimates of the number of entry points (and corresponding water systems) expected to exceed perchlorate levels of either 56 µg/L, 90 µg/L, or 18 µg/L and the number of people potentially exposed to perchlorate at different levels. The EPA is using these estimates to inform the Health Risk Reduction Cost Analysis presented in Section [REF _Ref531361870 \r \h].

The EPA used the UCMR 1 data as a key source of information for the occurrence analysis for the proposed perchlorate NPDWR. The EPA used the UCMR 1 data to estimate occurrence and exposure for the perchlorate regulatory determination. The Agency has modified the analysis of the UCMR 1 data set in response to concerns regarding UCMR 1 data quality and the actions some States have taken to regulate perchlorate in drinking water since the UCMR 1 data were generated. The EPA continues to rely on the UCMR 1 data because they are the best available data collected in accordance with accepted methods that provides a national assessment of perchlorate occurrence in drinking water. The UCMR 1 results are from a census of the large water systems (serving more than 10,000 people) and a statistically representative sample of small water systems. In 1999, the EPA developed the first round of the UCMR program in accordance with SDWA requirements to provide national occurrence information on unregulated contaminants (USEPA, 1999, 2000b). The UCMR 1 required sampling from systems in all 50 States, the District of Columbia, four U.S. territories, and tribal lands in five EPA Regions including:

- all 3,097 large (serving more than 10,000 people) CWSs and NTNCWSs, which analyzed either four quarterly samples collected at 3-month intervals (surface water sources), or two samples collected 5 to 7 months apart (ground water sources); and
- a statistically representative selection of 800 small CWSs and NTNCWSs, which analyzed either four quarterly samples collected at 3-month intervals (surface water sources) or two samples collected 5 to 7 months apart (ground water sources).

Water systems submitted UCMR 1 sampling results to EPA from 2001 until 2005. Water systems were required to analyze samples for 26 contaminants including perchlorate. The EPA established a minimum reporting level of 4 μg/L for perchlorate.

The EPA conducted a data quality review of the UCMR 1 data submitted by systems prior to analyzing the occurrence data for the 2011 perchlorate regulatory determination. The

UCMR 1 dataset used by the EPA included 34,331 samples with 637 measurements of perchlorate above the minimum reporting level from 3,865 systems.

The EPA conducted an additional data quality review in response to an Information Quality Guidelines Request for Correction submitted in 2012. As a result of this review, the EPA removed 199 source water samples (97 detections) that could be paired with a second follow-up sample located at the distribution system entry point. In these instances, the EPA determined the entry point sample was a better indicator of water quality provided to consumers than the source water sample. The Agency also determined that including both a source water and distribution system entry point for the same system would bias perchlorate occurrence estimates. Therefore, the EPA removed the source water sample from each pair. Thus, the final modified UCMR 1 occurrence data used for the proposed rule include 34,132 samples collected from 3,865 systems. The data include 540 measurements equal to or greater than the minimum reporting level at 149 systems. Table VI-1 shows sample distribution by system size category and measurement status. It also shows the number of entry points and systems where perchlorate measurements were reported. The entry point estimates differ from the system estimates because many water systems have more than one entry point. For example, a ground water system with two wells that has separate connections to the distribution system has two entry points.

The EPA has also reassessed the UCMR1 data in light of the adoption of regulatory limits in two States. Massachusetts promulgated a drinking water standard for perchlorate of 2 μg/L in 2006 [ADDIN ZOTERO_ITEM CSL_CITATION

{"citationID":"8DPpSrv3","properties":{"formattedCitation":"(MassDEP, 2006)","plainCitation":"(MassDEP, 2006)","noteIndex":0},"citationItems":[{"id":151,"uris":["http://zotero.org/groups/945096/items/9893MBZH"],"uri":["http://zotero.org/groups/945096/items/9893MBZH"],"itemData":{"id":151,"type":"personal_communication","title":"Letter to Public Water Suppliers concerning new perchlorate regulations","URL":"https://www.mass.gov/lists/perchlorate-background-information-and-standards#perchlorate---final-standards-","author":[{"literal":"MassDEP"}],"issued":{"date-parts":[["2006"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], and California promulgated a drinking water standard of 6 μg/L in 2007 [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"cfr6HNhg","properties":{"formattedCitation":"(California Department of Public Health, 2007)","plainCitation":"(California Department of Public Health, 2007)","noteIndex":0},"citationItems":[{"id":150,"uris":["http://zotero.org/groups/945096/items/RA45NKLQ"],"uri":["http://zotero.org/groups/945096/items/RA45NKLQ"],"itemData":{"id":150,"type":"personal_communication","title":"State Adoption of a Perchlorate Standard","URL":"https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/perchlorate/AdoptionMemotoWaterSystems-10-2007.pdf","author":[{"literal":"California Department of Public Health"}],"issued":{"date-parts":[["2007"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Systems in these States are now required to keep perchlorate levels in drinking water below their State limits, which are lower than the proposed MCL and alternative MCL. Therefore, UCMR 1 sampling results from systems in these States do not reflect the current occurrence and exposure conditions. For the purpose of estimating the costs and benefits of the proposed rule, the EPA assumed that no additional monitoring and treatment costs would be incurred by the systems in the States of California and Massachusetts. Systems in California account for some of the perchlorate measurements reported below. Notes in the tables below indicate whether results include or exclude systems in California and Massachusetts.

Table VI-1. UCMR 1 Data Summary Statistics

Item	Small System Sample	Large System Census	Sum
Total samples	3,295	30,837	34,132
Sample measurements ≥ 4 µg/L	15	525	540
Sample measurements ≥> 18 µg/L	1	16	17
Sample measurements ≥> 56 µg/L	0	2	2
Sample measurements > 90 µg/L	0	1	1
Total entry points	1,454	13,482	14,936
Entry points at which measurements ≥ 4 µg/L	8	328	336
Entry points at which measurements ≥> 18 µg/L	1	16	17
Entry points at which measurements ≥> 56 µg/L	0	2	2
Entry points at which measurements > 90 µg/L	0	1	1
Total systems	797	3,068	3,865
Systems at which measurements ≥ 4 µg/L	8	141	149
Systems at which measurements ≥> 18 µg/L	1	14	15
Systems at which measurements ≥> 56 µg/L	0	2	2
Systems at which measurements > 90 µg/L	0	1	1

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"UAoGFPZv","properties":{"formattedCitation":"(USEPA, 2018)","plainCitation":"(USEPA, 2018)","noteIndex":0},"citationItems":[{"id":969,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":969,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The total row counts and counts of measurements ≥ 4 µg/L identify all instances where perchlorate was detected at or above the minimum reporting level, including water systems in California and Massachusetts, which account for 537 systems in total and 51 systems at which measurements ≥4 µg/L. The instances where perchlorate measurements equal or exceed either 18 µg/L, 56µg/L, or 56µg90 µg/L exclude results from California and Massachusetts because water systems in these States must meet limits below 18 µg/L. The small system counts reflect sample results that have not been extrapolated to small systems nationwide.

Table VI-2 shows the service populations that correspond with the occurrence summary in Table VI-1. The entry point population estimates reflect the assumption that system population is uniformly distributed across entry points; e.g., the entry point population for a system with two entry points is one-half the total system population.

Table VI-2. UCMR1 Data Service Population Summary Statistics

Item	Small System Sample	Large System Census	Sum
Total entry point population	2,760,570	222,853,101	225,613,671
Population served by entry points at which measurements ≥ 4 µg/L	9,484	4,281,937	4,291,420
Population served by entry points at which measurements ~~≥~~> 18 µg/L	2,155	618,406	620,560
Population served by entry points at which measurements ~~≥~~> 56 µg/L	0	32,432	32,432
Population served by entry points at which measurements > 90 µg/L	0	25,972	25,972
Total system population	2,760,570	222,853,101	225,613,671
Population served by systems at which measurements ≥ 4 µg/L	13,483	16,159,082	16,172,565
Population served by systems at which measurements ~~≥~~>18 µg/L	4,309	696,871	701,180
Population served by systems at which measurements ~~≥~~> 56 µg/L	0	64,733	64,733
Population served by systems at which measurements > 90 µg/L	0	25,972	25,972

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ChxDKgDr","properties":{"formattedCitation":"(USEPA, 2018)","plainCitation":"(USEPA, 2018)","noteIndex":0},"citationItems":[{"id":969,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":969,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The populations for entry points/systems with measurements ≥ 4 µg/L identify all instances where perchlorate was detected at or above the minimum reporting level, including water systems in California and Massachusetts, which account for 39.6 million of the 225.6 million total population in UCMR 1, and 1.9 million of the 4.3 million population served by entry points at which measurements ≥4 µg/L. The instances where perchlorate measurements equal or exceed either 18 µg/L, 56µg/L, or ~~56µg~~90 µg/L exclude results from California and Massachusetts because water systems in these States must meet limits below 18 µg/L. The small system counts reflect sample results that have not been extrapolated to small systems nationwide.

As shown in the tables, 149 systems serving 16.2 million people had measured levels of perchlorate greater than the minimum reporting level. However, many of these systems have several entry points with no measured levels of perchlorate greater than the minimum reporting level; at the entry point level, the exposed population is approximately 4.3 million people served by 336 entry points. Because the uniform population distribution assumption may over or underestimate the service population of any particular entry point, the entry point estimates are uncertain. The system population estimates serve as upper bounds on exposure.

The EPA used entry point maximum measurements to estimate potential baseline occurrence and exposure at levels that exceed the proposed MCL and alternative MCL. The maximum measurements indicate perchlorate levels that occurred in at least one quarterly sample among surface water systems and at least one semi-annual sample among ground water systems.

[REF _Ref529966860 \h] ~~and~~ [REF _Ref529966868 \h]Table VI-3 through Table VI-5 show the occurrence and exposure estimates based on the 56 µg/L ~~and~~, 18 µg/L MCL, and 90 µg/L values, respectively. Each table provides estimates of the entry points at which the maximum perchlorate concentrations exceed the MCL value. The tables also report the system-level information for these entry points.

Table VI-3: Estimated Perchlorate Occurrence and Exposure: Entry Point Max Exceeds 56 µg/L

Affected Entity	Small Systems	Large Systems	Total Systems
Entry points	0	2	2
Population served	0	32,432	32,432
Water systems	0	2	2
Population served	0	64,733	64,733

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"adhRbcXq","properties":{"formattedCitation":"(USEPA, 2018c)","plainCitation":"(USEPA, 2018c)","noteIndex":0},"citationItems":[{"id":155,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":155,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Table VI-4: Estimated Perchlorate Occurrence and Exposure: Entry Point Max Exceeds 18 µg/L

Affected Entity	Small Systems[1]	Large Systems	Total Systems
Entry points	1	16	17
Population served	2,155	618,406	620,560
Water systems	1	14	15
Population served	4,309	696,871	701,180

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"z4saRTHP","properties":{"formattedCitation":"(USEPA, 2018c)","plainCitation":"(USEPA, 2018c)","noteIndex":0},"citationItems":[{"id":155,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":155,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

1. The values shown in the table are estimates based on the UCMR 1 data. The EPA also applied the statistical sampling weights to the results to extrapolate results to national results. The entry point at which a measurement exceeds 18 µg/L is one of 20 in its sample stratum; no other sample in the stratum had a measurement of perchlorate greater than the minimum reporting level. The entry point population of 2,155 represents 5.31% of the total population served by the six UCMR 1 systems in the stratum (40,574). Currently, the stratum population of 774,780 accounts for 1.32% of the 58.7 million national population served by small systems. Thus, the UCMR 1 results indicate that 0.07% (5.31% x 1.32%) of small system customers (approximately 41,100) may be exposed to perchlorate greater than 18 µg/L.

Table VI-5: Estimated Perchlorate Occurrence and Exposure: Entry Point Max Exceeds 90 µg/L

Affected Entity	Small Systems[1]	Large Systems	Total Systems
Entry points	0	1	1
Population served	0	25,972	25,972
Water systems	0	1	1
Population served	0	25,972	25,972

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"z4saRTHP","properties":{"formattedCitation":"(USEPA, 2018c)","plainCitation":"(USEPA, 2018c)","noteIndex":0},"citationItems":[{"id":155,"uris":["http://zotero.org/groups/945096/items/YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":155,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

The Perchlorate Occurrence and Monitoring Report [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"HbxFrtl3","properties":{"formattedCitation":"(USEPA, 2018)","plainCitation":"(USEPA, 2018)","noteIndex":0},"citationItems":[{"id":969,"uris":["http://zotero.org/groups/945096/items/

YERQWPRZ"],"uri":["http://zotero.org/groups/945096/items/YERQWPRZ"],"itemData":{"id":969,"type":"article","title":"Perchlorate Occurrence and Monitoring Report","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] describes other perchlorate data sources; including: ambient water quality data from the U.S. Geological Survey (USGS) National Water-Quality Assessment (NAWQA) program, USGS National Water Information System (NWIS) Database, the EPA's Storage and Retrieval (EPA STORET) Data Warehouse; three regional studies along the Lower Colorado River; and system monitoring data from several States and organizations.

VII. Analytical Methods

The SDWA directs the EPA to set a contaminant's MCL as close to its MCLG as is ''feasible'', the definition of which includes an evaluation of the feasibility of performing chemical analysis of the contaminant at standard drinking water laboratories. Specifically, SDWA directs the EPA to determine that it is economically and technologically feasible to ascertain the level of the contaminant being regulated in water in public water systems (Section 1401(1)(C)(i)). NPDWRs are also to contain ''criteria and procedures to assure a supply of drinking water which dependably complies with such [MCLs]; including accepted methods for quality control and testing procedures to insure compliance with such levels.'' (Section 1401(1)(D)).

To comply with these requirements, the EPA considers method performance under relevant laboratory conditions, their likely prevalence in certified drinking water laboratories, and the associated analytical costs. The EPA has developed five analytical methods for the identification and quantification of perchlorate in drinking water that meet these criteria. The proposed EPA methods for perchlorate are: 314.0, 314.1, 314.2, 331.0, and 332.0. The EPA estimates that laboratory analytical monitoring costs range from $55 to $64 per each sampling event. A detailed description of these methods is presented in the Perchlorate Occurrence and Monitoring Report ((USEPA, 2018c).

The EPA Methods 314.0, 314.1, 314.2, 331.0, and 332.0 underwent the EPA's analytical method development and validation processes. The validation process includes a protocol for modifications to any existing EPA-approved analytical methods and a protocol for new determinative techniques. Both validation protocols are rigorous and consider many technical aspects of analytical method performance, including: detection limits; instrument calibration; precision and analyte recovery; analyte retention times; evaluation of blanks; development of Quality Control acceptance criteria; analysis of field samples; and other technical aspects of sample analysis and data reporting. All of the proposed EPA analytical methods provide performance data to demonstrate their capability to reliably and consistently measure perchlorate in drinking water at the proposed and alternate MCLs.

VIII. Monitoring and Compliance Requirements

A. What are the Proposed Monitoring Requirements?

If EPA issues a final NPDWR for perchlorate, the EPA is proposing to require CWS and NTNCWSs to monitor for perchlorate in accordance with the standardized monitoring framework. Public water systems must sample entry points to the distribution system consistent with requirements in 40 CFR 141.23(a).

Under the Standardized Monitoring Framework, the monitoring frequency for a public water system is dependent on previous monitoring results and whether a monitoring waiver has been granted. Monitoring frequencies may be quarterly, annually, once every three years or once every nine years, in the case of a waiver. If a water system exceeds the perchlorate MCL, the system is in violation and triggered into quarterly monitoring for that sampling point ``in the next quarter after the violation occurred (40 CFR 141.23(c)(7))." The State may allow the system to return to the routine monitoring frequency when the State determines that the system is reliably and consistently below the MCL. However, the State cannot make a determination that the system is reliably and consistently below the MCL until a minimum of 2 consecutive ground water or 4 consecutive surface water samples have been collected (40 CFR 141.23(c)(8)). All systems must comply with the sampling requirements, unless a waiver has been granted in writing by the State (40 CFR 141.23(c)(6)).

B. Can States Grant Monitoring Waivers?

Under the proposal, water systems may apply to the State, and States may grant, a 9-year monitoring waiver if the conditions described in 40 CFR 141.23(c)(3)-(6) are met. A State may grant a waiver for surface water systems after three rounds of annual monitoring with results less than the MCL and for groundwater systems after conducting three rounds of monitoring with results less than the MCL. One sample must be collected during the nine-year compliance cycle that the waiver is effective, and the waiver must be renewed every nine years.

C. How are System MCL Violations Determined?

If EPA issues a final NPDWR for perchlorate, violations of the perchlorate MCL will be determined in a manner consistent with 40 CFR 141.23(i)(3). Compliance with the MCL is determined based on one sample if the level is below the MCL. If the level of perchlorate exceeds the MCL at any entry point in the initial sample, a confirmation sample is required within two weeks of the system's receipt of notification of the analytical result of the first sample, in accordance with 141.23(f)(1). Compliance shall be determined based on the average of the initial and confirmation samples.

D. When Must Systems Complete Initial Monitoring?

Pursuant to Section 1412(b)(10), this rule would be effective three years after promulgation. To satisfy initial monitoring requirements, CWS serving populations greater than 10,000 persons must collect 4 quarterly samples during the first compliance period of the fourth compliance cycle (January 1, 2023– December 31, 2025) of the standardized monitoring framework. NTNCWS and CWSs serving 10,000 persons or less must collect 4 quarterly samples during the second compliance period of the fourth compliance cycle (January 1, 2026 – December 31, 2028) of the standardized monitoring framework.

E. Can Systems use Grandfathered Data to Satisfy the Initial Monitoring Requirements?

As proposed today, systems would be allowed to use grandfathered data collected after January 1, 2020 to satisfy the initial monitoring requirements. To satisfy initial monitoring requirements, a system with appropriate historical monitoring data for each entry point to the distribution system could use the monitoring data from the compliance monitoring period between January 1, 2020 and December 31, 2022 for community water systems serving greater than 10,000 persons and between January 1, 2023 and December 31, 2025 for non-transient non-community water systems and for community water systems serving 10,000 or fewer persons.

IX. Safe Drinking Water Act Right to Know Requirements

A. What are the Consumer Confidence Report Requirements?

Community water systems must prepare and deliver an annual Consumer Confidence Report in accordance with requirements in 40 CFR 141 Subpart O.

B. What are the Public Notification Requirements?

All public water systems must give notice for all violations of national primary drinking water regulations and for other situations. Under this proposal, violations of the perchlorate MCL would be designated as Tier 1 and as such, public water systems would be required to comply with 40 CFR 141.202. As described in Section III of this proposal, fetuses of first trimester pregnant women with low iodine are the most sensitive subpopulation, therefore, notification of an MCL violation should be provided as soon as practicable but no later than 24 hours after the system learns of the violation.

X. Treatment Technologies

Systems that exceed the perchlorate MCL will need to adopt new treatment or another strategy to reduce perchlorate to a level that meets the MCL. When the EPA establishes an MCL for a drinking water contaminant, Section 1412(b)(4)(E) of the SDWA requires that the Agency "list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting [the MCL]," which are referred to as best available technologies (BAT). These BATs are used by States to establish conditions for source water variances under Section 1415(a). Furthermore, Section 1412(b)(4)(E)(ii) requires that the Agency identify small system compliance technologies (SSCT), which are affordable treatment technologies, or other means that can achieve compliance with the MCL (or treatment technique, where applicable). The lack of an affordable SSCT for a contaminant triggers certain additional procedures which can result in States issuing small system variances under Section 1412(e).

A. What are the Best Available Technologies?

The Agency identifies the best available technologies (BAT) as those meeting the following criteria: (1) the capability of a high removal efficiency; (2) a history of full-scale operation; (3) general geographic applicability; (4) reasonable cost based on large and metropolitan water systems; (5) reasonable service life; (6) compatibility with other water treatment processes; and (7) the ability to bring all of the water in a system into compliance. The Agency is proposing the following technologies as BAT for removal of perchlorate from drinking water based its review of the treatment and cost literature (USEPA, 2018a):

- ion exchange;
- biological treatment; and
- centralized reverse osmosis.

There are also non-treatment options that might be used for compliance in lieu of installing and operating treatment technologies. These include blending existing water sources, replacing a perchlorate-contaminated source of drinking water with a new source (e.g., a new well), and purchasing compliant water from another system. Below are brief descriptions of each proposed BAT.

Ion Exchange.

Ion exchange is a physical and chemical separation process that can achieve high perchlorate removal rates. Feed water passes through a vessel containing a bed of resin made of synthetic beads or gel. As feed water moves through the resin, an ionic contaminant such as perchlorate exchanges for an ion (typically chloride) on the resin. Demonstrated removal efficiencies for perchlorate are typically in the high 90 percent range and can achieve concentrations less than 4 μg/L in treated water [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"s9dVZckb","properties":{"formattedCitation":"(Drago & Leserman, 2011; Membrane Technology, 2006; Siemens Water Technologies, 2009; The Interstate Technology & Regulatory Council (ITRC) Team, 2008)","plainCitation":"(Drago & Leserman, 2011; Membrane Technology, 2006; Siemens Water Technologies, 2009; The Interstate Technology & Regulatory Council (ITRC) Team, 2008)","noteIndex":0},"citationItems":[{"id":1048,"uris":["http://zotero.org/groups/945096/items/KIPNEQUM"],"uri":["http://zotero.org/groups/945096/items/KIPNEQUM"],"itemData":{"id":1048,"type":"paper-conference","title":"Castaic Lake Water Agency Operating Experience with Lead-Lag Anion Exchange for Perchlorate Removal","container-title":"Proceedings of the American Water Works Association Water Quality Technology Conference","event":"Water Quality Technology Conference","author":[{"family":"Drago","given":"J.A."},{"family":"Leserman","given":"J.R."}],"issued":{"date-parts":[["2011",11]]}}},{"id":1154,"uris":["http://zotero.org/groups/945096/items/2DBS6UYD"],"uri":["http://zotero.org/groups/945096/items/2DBS6UYD"],"itemData":{"id":1154,"type":"article","title":"News: Ion=Exchange System Removes Perchlorate","publisher":"Membrane Technology","author":[{"literal":"Membrane Technology"}],"issued":{"date-parts":[["2006",4]]}}},{"id":1125,"uris":["http://zotero.org/groups/945096/items/6WYYWFY2"],"uri":["http://zotero.org/groups/945096/items/6WYYWFY2"],"itemData":{"id":1125,"type":"report","title":"Case Study: Municipality in the State of Massachusetts","author":[{"literal":"Siemens Water Technologies"}],"issued":{"date-parts":[["2009"]]}}},{"id":1118,"uris":["http://zotero.org/groups/945096/items/5PV8GPIA"],"uri":["http://zotero.org/groups/945096/items/5PV8GPIA"],"itemData":{"id":1118,"type":"article","title":"Technical/Regulatory Guidance: Remediation Technologies for Perchlorate Contamination in Water and

Soil","URL":"http://www.eosremediation.com/download/Perchlorate/ITRC%20PERC-2.pdf","author":[{"literal":"The Interstate Technology & Regulatory Council (ITRC) Team"}],"issued":{"date-parts":[["2008",3]]},"accessed":{"date-parts":[["2018",10,13]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The operation continues until enough of the resin's available ion exchange sites have ions from the feed water and the resin no longer effectively removes the target contaminant, i.e., the contaminant 'breaks through" the treatment process. At this point, the resin must be disposed and replaced or regenerated. The length of time until resin must be replaced or regenerated is known as bed life and is a critical factor in the cost effectiveness of ion exchange as a treatment technology. One measurement of bed life is the volume of water that can be treated before breakthrough – called bed volumes – the number of times the resin bed can be filled before breakthrough. Several factors affect bed life, including the presence of competing ions such as nitrate and the type of resin used. Resin types tested for perchlorate removal include strong-base polyacrylic, strong-base polystyrenic (including nitrate-selective), weak-base polyacrylic, weak-base polystyrenic, and perchlorate-selective. Based on studies of the effect of competing ions on performance, perchlorate-selective resins can achieve bed lives ranging from 105,000 to 170,000 bed volumes [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"cxQjBTo8","properties":{"formattedCitation":"(Blute, Seidel, McGuire, Qin, & Byerrum, 2006; Russell, Qin, Blute, McGuire, & Williams, 2008; Wu & Blute, 2010)","plainCitation":"(Blute, Seidel, McGuire, Qin, & Byerrum, 2006; Russell, Qin, Blute,

McGuire, & Williams, 2008; Wu & Blute,

2010)","noteIndex":0},"citationItems":[{"id":1076,"uris":["http://zotero.org/groups/945096/items/8Z7K9ZUJ"],"uri":["http://zotero.org/groups/945096/items/8Z7K9ZUJ"],"itemData":{"id":1076,"type":"speech","title":"Bench and Pilot Testing of High Capacity, Single-Pass Ion Exchange Resins for Perchlorate Removal","publisher-place":"San Antonio, TX","event":"2006 AWWA Annual Conference & Exposition","event-place":"San Antonio, TX","author":[{"family":"Blute","given":"N.K."},{"family":"Seidel","given":"C.J."},{"family":"McGuire","given":"M.J."},{"family":"Qin","given":"D."},{"family":"Byerrum","given":"J."}],"issued":{"date-parts":[["2006",6]]}}},{"id":1132,"uris":["http://zotero.org/groups/945096/items/NLAFHBV2"],"uri":["http://zotero.org/groups/945096/items/NLAFHBV2"],"itemData":{"id":1132,"type":"speech","title":"Pilot Testing of Single Pass Perchlorate-Selective Ion Exchange Resins at Three Utilities in the Main San Gabriel Basin","publisher-place":"Cincinnati, OH","event":"AWWA Water Quality Technology Conference & Exposition","event-place":"Cincinnati, OH","author":[{"family":"Russell","given":"C.G."},{"family":"Qin","given":"G."},{"family":"Blute","given":"N.K."},{"family":"McGuire","given":"M.J."},{"family":"Williams","given":"C."}],"issued":{"date-parts":[["2008",11]]}}},{"id":1094,"uris":["http://zotero.org/groups/945096/items/2QPEXW23"],"uri":["http://zotero.org/groups/945096/items/2QPEXW23"],"itemData":{"id":1094,"type":"speech","title":"Perchlorate Removal Using Single-Pass Ion Exchange Resin - Pilot Testing Purolite

A532E at the San Gabriel B6 Plant","publisher-place":"Hollywood, CA","event":"2010 California-Nevada AWWA Spring Conference","event-place":"Hollywood, CA","author":[{"family":"Wu","given":"X."},{"family":"Blute","given":"N.K."}],"issued":{"date-parts":[["2010",3,31]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Perchlorate-selective resin cannot be easily regenerated for reuse; the exhausted resin must be disposed. This mode of operation, however, avoids the production of liquid residuals in the form of spent regenerant. Therefore, in combination with the long bed life, single-use perchlorate-selective ion exchange can be a cost-effective treatment option in spite of the need to dispose of the perchlorate-contaminated resin. Build-up of arsenic or uranium on the resin may affect waste disposal options, although studies of perchlorate-selective resins show that arsenic concentrations remain below regulatory limits for hazardous waste disposal and uranium concentrations generally remain below those that require special handling as radioactive waste [ADDIN ZOTERO_ITEM CSL_CITATION
{"citationID":"I0SaZZiL","properties":{"formattedCitation":"(Blute et al., 2006; Russell et al., 2008; Wu & Blute, 2010)","plainCitation":"(Blute et al., 2006; Russell et al., 2008; Wu & Blute, 2010)","noteIndex":0},"citationItems":[{"id":1076,"uris":["http://zotero.org/groups/945096/items/8Z7K9ZUJ"],"uri":["http://zotero.org/groups/945096/items/8Z7K9ZUJ"],"itemData":{"id":1076,"type":"speech","title":"Bench and Pilot Testing of High Capacity, Single-Pass Ion Exchange Resins for Perchlorate Removal","publisher-place":"San Antonio, TX","event":"2006 AWWA

Annual Conference & Exposition","event-place":"San Antonio, TX","author":[{"family":"Blute","given":"N.K."},{"family":"Seidel","given":"C.J."},{"family":"McGuire","given":"M.J."},{"family":"Qin","given":"D."},{"family":"Byerrum","given":"J."}],"issued":{"date-parts":[["2006",6]]}}},{"id":1132,"uris":["http://zotero.org/groups/945096/items/NLAFHBV2"],"uri":["http://zotero.org/groups/945096/items/NLAFHBV2"],"itemData":{"id":1132,"type":"speech","title":"Pilot Testing of Single Pass Perchlorate-Selective Ion Exchange Resins at Three Utilities in the Main San Gabriel Basin","publisher-place":"Cincinnati, OH","event":"AWWA Water Quality Technology Conference & Exposition","event-place":"Cincinnati, OH","author":[{"family":"Russell","given":"C.G."},{"family":"Qin","given":"G."},{"family":"Blute","given":"N.K."},{"family":"McGuire","given":"M.J."},{"family":"Williams","given":"C."}],"issued":{"date-parts":[["2008",11]]}}},{"id":1094,"uris":["http://zotero.org/groups/945096/items/2QPEXW23"],"uri":["http://zotero.org/groups/945096/items/2QPEXW23"],"itemData":{"id":1094,"type":"speech","title":"Perchlorate Removal Using Single-Pass Ion Exchange Resin - Pilot Testing Purolite A532E at the San Gabriel B6 Plant","publisher-place":"Hollywood, CA","event":"2010 California-Nevada AWWA Spring Conference","event-place":"Hollywood, CA","author":[{"family":"Wu","given":"X."},{"family":"Blute","given":"N.K."}],"issued":{"date-parts":[["2010",3,31]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Ion exchange can increase the corrosivity of treated water [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"dcLyBjzj","properties":{"formattedCitation":"(Berlien, 2003; Betts, 1998; USEPA, 2005b)","plainCitation":"(Berlien, 2003; Betts, 1998; USEPA, 2005b)","noteIndex":0},"citationItems":[{"id":1079,"uris":["http://zotero.org/groups/945096/items/8PB22K95"],"uri":["http://zotero.org/groups/945096/items/8PB22K95"],"itemData":{"id":1079,"type":"report","title":"La Puente Valley County Water District's Experience with ISEP","collection-title":"Presentation of Carollo Engineers, Inc. and Association of California Water Agencies","author":[{"family":"Berlien","given":"M.J."}],"issued":{"date-parts":[["2003",4]]}}},{"id":1078,"uris":["http://zotero.org/groups/945096/items/BNWD5VQP"],"uri":["http://zotero.org/groups/945096/items/BNWD5VQP"],"itemData":{"id":1078,"type":"article-journal","title":"Rotation ion-exchange system removes perchlorate","page":"454A-455A","volume":"32","journalAbbreviation":"Environ. Sci. Technol.","author":[{"family":"Betts","given":"K.S."}],"issued":{"date-parts":[["1998"]]}}},{"id":1208,"uris":["http://zotero.org/groups/945096/items/EWAQ4GEK"],"uri":["http://zotero.org/groups/945096/items/EWAQ4GEK"],"itemData":{"id":1208,"type":"article","title":"Perchlorate Treatment Technology Update: Federal Facilities Forum Issue Paper","publisher":"Office of Solid Waste and Emergency Response. EPA 542-R-05-015","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2005",5]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] because of the addition of chloride ions and/or removal of carbonates and bicarbonates. Such instances can be addressed by adding or adjusting corrosion control.

Biological Treatment.

Biological treatment uses bacteria to reduce perchlorate to chlorate, chlorite, chloride, and oxygen. Biological treatment can destroy the perchlorate ion, eliminating the need for management of perchlorate-bearing waste streams. Removal effectiveness exceeds 90 percent for bench- and full-scale tests [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"CnYkqct9","properties":{"formattedCitation":"(Kotlarz, Upadhyaya, Togna, & Raskin, 2016; Upadhyaya, Kotlarz, Togna, & Raskin, 2015; U.S. Department of Defense (U.S. DoD), 2008, 2009; T. D. Webster & Crowley, 2010, 2016; T. D. Webster & Litchfield, 2017)","plainCitation":"(Kotlarz, Upadhyaya, Togna, & Raskin, 2016; Upadhyaya, Kotlarz, Togna, & Raskin, 2015; U.S. Department of Defense (U.S. DoD), 2008, 2009; T. D. Webster & Crowley, 2010, 2016; T. D. Webster & Litchfield, 2017)","noteIndex":0},"citationItems":[{"id":1019,"uris":["http://zotero.org/groups/945096/items/E5WRR4HD"],"uri":["http://zotero.org/groups/945096/items/E5WRR4HD"],"itemData":{"id":1019,"type":"article-journal","title":"Evaluation of electron donors for biological perchlorate removal highlights the importance of diverse perchlorate-reducing populations","container-title":"Environmental Science: Water Research & Technology","page":"1049-1063","volume":"2","author":[{"family":"Kotlarz","given":"N."},{"family":"Upadhyaya","given":"G."},{"family":"Togna","given":"P."},{"family":"Raskin","given":"L."}],"issued":{"date-parts":[["2016"]]}}},{"id":1106,"uris":["http://zotero.org/groups/945096/items/KLWCLIE4"],"uri":["http://zotero.org/groups/945096/items/KLWCLIE4"],"itemData":{"id":1106,"type":"article-journal","title":"Carbohydrate-Based Electron Donor for Biological Nitrate and Perchlorate Removal From Drinking Water","container-title":"Journal - American Water Works Association","page":"E674-E684","volume":"107","issue":"12","source":"Wiley Online Library","abstract":"This study evaluated the feasibility of replacing acetic acid with a commercial carbohydrate-based electron donor (CBED) for removal of nitrate and perchlorate (ClO4–) from drinking water. Bench-scale biologically active carbon fixed-bed and fluidized-bed reactors (FXBR and FLBR, respectively), with an initial empty bed contact time (EBCT) of 42.8 min, were fed simulated groundwater containing 15 mg/L nitrate as nitrogen and 200 µg/L ClO4–. EBCT in the FLBR after final expansion was 80.5 min. During the first 100 days using acetic acid at 125 mg/L chemical oxygen demand (COD), complete nitrate removal was achieved in both systems, whereas perchlorate in the FXBR and FLBR effluents remained below 3 and 6 µg/L ClO4–, respectively. For comparable removals, influent COD requirement was higher with the CBED. Biomass yields with acetic acid and the CBED were 0.54–0.58 and 0.59–0.74 mg CODbiomass/mg CODsubstrate, respectively. The higher yield with the CBED resulted in more frequent maintenance requirements.","DOI":"10.5942/jawwa.2015.107.0143","ISSN":"1551-8833","language":"en","author":[{"family":"Upadhyaya","given":"Giridhar"},{"family":"Kotlarz","given":"Nadine"},{"family":"Togna","given":"Paul"},{"family":"Raskin","given":"Lutgarde"}],"issued":{"date-parts":[["2015",12,1]]}}},{"id":1110,"uris":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"uri":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"itemData":{"id":1110,"type":"report","title":"Perchlorate Removal, Destruction, and Field Monitoring Demonstration (Drinking Water - Pilot Scale)","collection-title":"ESTCP Cost and Performance Report (ER-0312)","author":[{"literal":"U.S. Department of Defense (U.S. DoD)"}],"issued":{"date-parts":[["2008"]]}}},{"id":1116,"uris":["http://zotero.org/groups/945096/items/9FHLVTXY"],"uri":["http://zotero.org/groups/945096/items/9FHLVTXY"],"itemData":{"id":1116,"type":"report","title":"Demonstration of a Full-Scale Fluidized Bed Bioreactor for the Treatment of Perchlorate at Low Concentrations in Groundwater","genre":"Environmental Security Technology Certification Program (ESTCP) Final Report (ER-0543)","author":[{"family":"U.S. Department of Defense (U.S. DoD)","given":""}],"issued":{"date-parts":[["2009"]]}}},{"id":1093,"uris":["http://zotero.org/groups/945096/items/BI7SF8HW"],"uri":["http://zotero.org/groups/945096/items/BI7SF8HW"],"itemData":{"id":1093,"type":"speech","title":"Full-Scale Implementation of a Biological Fluidized Bed Drinking Water Treatment Plant for Nitrate and Perchlorate Treatment","publisher-place":"Ontario, CA","event":"2010 Water Education Foundation Water Quality and Regulatory Conference","event-place":"Ontario, CA","author":[{"family":"Webster","given":"T.D."},{"family":"Crowley","given":"T.J."}],"issued":{"date-parts":[["2010",11,3]]}}},{"id":989,"uris":["http://zotero.org/groups/945096/items/BI5LYMZP"],"uri":["http://zotero.org/groups/945096/items/BI5LYMZP"],"itemData":{"id":989,"type":"spee ch","title":"Biological treatment of perchlorate in groundwater.","event":"AWWA Annual Conference and Exposition","author":[{"family":"Webster","given":"T.D."},{"family":"Crowley","given":"T.J."}],"issued":{"date-parts":[["2016",6,21]]}}},{"id":990,"uris":["http://zotero.org/groups/945096/items/64HZKA2M"],"uri":["http://zotero.org/groups/945096/items/64HZKA2M"],"itemData":{"id":990,"type":"article-journal","title":"Full-scale biological treatment of nitrate and perchlorate for potable water production","container-title":"Journal AWWA","page":"30-40","volume":"109","issue":"5","author":[{"family":"Webster","given":"T.D."},{"family":"Litchfield","given":"M.H."}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Although biological treatment is a relatively new technology for treatment of drinking water in the United States, the State of California has identified biological treatment (along with ion exchange) as one of two best available technologies for achieving compliance with its standard for perchlorate in drinking water (California Code of Regulations, Title 22, Chapter 15, Section 64447.2). The California BAT specifies a fluidized bed, although studies suggest that a fixed bed is also effective. The first full-scale fluidized bed facility using biological treatment of perchlorate to supply municipal drinking water began operation in 2016 [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"nKwIqjde","properties":{"formattedCitation":"(T. D. Webster & Crowley, 2016;

T. D. Webster & Litchfield, 2017)","plainCitation":"(T. D. Webster & Crowley, 2016; T. D. Webster & Litchfield, 2017)","noteIndex":0},"citationItems":[{"id":989,"uris":["http://zotero.org/groups/945096/items/BI5LYMZP"],"uri":["http://zotero.org/groups/945096/items/BI5LYMZP"],"itemData":{"id":989,"type":"speech","title":"Biological treatment of perchlorate in groundwater.","event":"AWWA Annual Conference and Exposition","author":[{"family":"Webster","given":"T.D."},{"family":"Crowley","given":"T.J."}],"issued":{"date-parts":[["2016",6,21]]}}},{"id":990,"uris":["http://zotero.org/groups/945096/items/64HZKA2M"],"uri":["http://zotero.org/groups/945096/items/64HZKA2M"],"itemData":{"id":990,"type":"article-journal","title":"Full-scale biological treatment of nitrate and perchlorate for potable water production","container-title":"Journal AWWA","page":"30-40","volume":"109","issue":"5","author":[{"family":"Webster","given":"T.D."},{"family":"Litchfield","given":"M.H."}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Raw water quality will affect process design, in particular, temperature affects the rate of biomass growth; at temperatures below 10 degrees Celsius, growth is inhibited and bioremediation becomes infeasible [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ISPg08cl","properties":{"formattedCitation":"(Dugan, 2010b, 2010a; Dugan et al., 2009)","plainCitation":"(Dugan, 2010b, 2010a; Dugan et al., 2009)","noteIndex":0},"citationItems":[{"id":1047,"uris":["http://zotero.org/groups/945096/items/X3WWHCXS"],"uri":["http://zotero.org/groups/945096/items/X3WWHCXS"],"itemData":{"id":1047,"type":"speech","title":"The Impact of Temperature on Biological Perchlorate Removal and Downstream Effluent Polishing","publisher-place":"U.S. Environmental Protection Agency, Office of Research and Development, National Risk Management Research Laboratory","event-place":"U.S. Environmental Protection Agency, Office of Research and Development, National Risk Management Research Laboratory","author":[{"family":"Dugan","given":"N.R."}],"issued":{"date-parts":[["2010",12,8]]}}},{"id":1046,"uris":["http://zotero.org/groups/945096/items/IIXUW45F"],"uri":["http://zotero.org/groups/945096/items/IIXUW45F"],"itemData":{"id":1046,"type":"article","title":"Supporting data for presentation: The Impact of Temperature on Biological Perchlorate Removal and Downstream Effluent Polishing","publisher":"U.S. Environmental Protection Agency, Office of Research and Development, National Risk Management Research Laboratory","author":[{"family":"Dugan","given":"N.R."}],"issued":{"date-parts":[["2010",12,8]]}}},{"id":1045,"uris":["http://zotero.org/groups/945096/items/FLVLSXCS"],"uri":["http://zotero.org/groups/945096/items/FLVLSXCS"],"itemData":{"id":1045,"type":"speech","title":"The Impact of Temperature on Anaerobic Biological Perchlorate Treatment","publisher-place":"Seattle, WA","event":"2009 AWWA Water Quality Technology Conference & Exposition","event-place":"Seattle, WA","author":[{"family":"Dugan","given":"N.R."},{"family":"Williams","given":"D.J."},{"fam ily":"Meyer","given":"M."},{"family":"Schneider","given":"R.R."},{"family":"Speth","given":"T.F."},{"family":"Metz","given":"D.H."}],"issued":{"date-parts":[["2009"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. This factor limits the feasibility of biological treatment in areas that experience low water temperatures during winter. In addition, bacteria in bioreactors require nutrients to grow and effectively reduce perchlorate. Therefore, some source waters may require supplemental addition of nutrients such as nitrogen or phosphorus [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"NDoHjLOr","properties":{"formattedCitation":"(Harding Engineering and Environmental Services (ESE), 2001; U.S. Department of Defense (U.S. DoD), 2008a, 2009)","plainCitation":"(Harding Engineering and Environmental Services (ESE), 2001; U.S. Department of Defense (U.S. DoD), 2008a, 2009)","noteIndex":0},"citationItems":[{"id":1139,"uris":["http://zotero.org/groups/945096/items/ZPGXUZPL"],"uri":["http://zotero.org/groups/945096/items/ZPGXUZPL"],"itemData":{"id":1139,"type":"report","title":"Final: Phase 2 Treatibility Study Report, Aerojet GET E/F Treatment Facility, Sacramento, California","collection-title":"Prepared for U.S. Environmental Protection Agency Region IX and Baldwin Park Operable Unit Cooperating Respondents, San Gabriel Basin,California","author":[{"family":"Harding Engineering and Environmental Services (ESE)","given":""}],"issued":{"date-parts":[["2001"]]}}},{"id":1074,"uris":["http://zotero.org/groups/945096/items/2ZCNIFHT"],"ur i":["http://zotero.org/groups/945096/items/2ZCNIFHT"],"itemData":{"id":1074,"type":"report","title":"Direct Fixed-bed Biological Perchlorate Destruction Demonstration","genre":"ESTCP Final Report (ER-0544)","author":[{"literal":"U.S. Department of Defense (U.S. DoD)"}],"issued":{"date-parts":[["2008",9,25]]}}},{"id":1081,"uris":["http://zotero.org/groups/945096/items/9FHLVTXY"],"uri":["http://zotero.org/groups/945096/items/9FHLVTXY"],"itemData":{"id":1081,"type":"report","title":"Demonstration of a Full-Scale Fluidized Bed Bioreactor for the Treatment of Perchlorate at Low Concentrations in Groundwater","genre":"Environmental Security Technology Certification Program (ESTCP) Final Report (ER-0543)","author":[{"family":"U.S. Department of Defense (U.S. DoD)","given":""}],"issued":{"date-parts":[["2009"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Although the process does not produce perchlorate-contaminated wastes, periodic removal of excess biomass, e.g., through backwash, will be required. The backwash water is non-toxic and can be discharged to a sanitary sewer [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"f4qlOob5","properties":{"formattedCitation":"(U.S. Department of Defense (U.S. DoD), 2008, 2009)","plainCitation":"(U.S. Department of Defense (U.S. DoD), 2008, 2009)","noteIndex":0},"citationItems":[{"id":1110,"uris":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"uri":["http://zotero.org/groups/945096/items/VE5JI4GQ"],"itemData":{"id":111

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Reverse Osmosis.

Reverse osmosis is a membrane filtration process that physically removes perchlorate ions from drinking water. This process separates a solute such as perchlorate ions from a solution by forcing the solvent to flow through a membrane at a pressure greater than the normal osmotic pressure. The membrane is semi-permeable, transporting different molecular species at different rates. Water and low-molecular weight solutes pass through the membrane and are removed as permeate, or filtrate. Dissolved and suspended solids are rejected by the membrane and are removed as concentrate or reject. This technique does not destroy the perchlorate ion and, therefore, creates a subsequent need for disposal or treatment of perchlorate-contaminated waste (the concentrate).

Membranes may remove ions from feed water by a sieving action (called steric exclusion), or by electrostatic repulsion of ions from the charged membrane surface. Across multiple bench- and pilot-scale studies, reverse osmosis membranes consistently achieve perchlorate removal greater than 80 percent and up to 98 percent [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"edXX3GgQ","properties":{"formattedCitation":"(Liang, Scott, Palencia, & Bruno, 1998; Nam et al., 2005; Yoon, Amy, & Yoon, 2005; Yoon, Yoon, Amy, & Her, 2005)","plainCitation":"(Liang, Scott, Palencia, & Bruno, 1998; Nam et al., 2005; Yoon, Amy, & Yoon, 2005; Yoon, Yoon, Amy, & Her, 2005)","noteIndex":0},"citationItems":[{"id":985,"uris":["http://zotero.org/groups/945096/items/IQVVPD73"],"uri":["http://zotero.org/groups/945096/items/IQVVPD73"],"itemData":{"id":985, "type":"paper-conference","title":"Investigation of Treatment Options for Perchlorate Removal.","publisher":"La Verne, CA: Metropolitan Water District of Southern California","publisher-place":"San Diego, CA","event":"AWWA Water Quality Technology Conference","event-place":"San Diego, CA","author":[{"family":"Liang","given":"S."},{"family":"Scott","given":"K.N."},{"family":"Palencia","given":"L.S."},{"family":"Bruno","given":"J."}],"issued":{"date-parts":[["1998"]]}}},{"id":986,"uris":["http://zotero.org/groups/945096/items/YHEV76YW"],"uri":["http://zotero.org/groups/945096/items/YHEV76YW"],"itemData":{"id":986,"type":"paper-conference","title":"Perchlorate Rejection by High-Pressure Membranes and Brine Stream Treatment by Chemical and Biological Processes.","publisher-place":"Phoenix, AZ","event":"American Water Works Association Membrane Technology Conference","event-place":"Phoenix, AZ","author":[{"family":"Nam","given":"S."},{"family":"Kim","given":"S."},{"family":"Choi","given":"H."},{"family":"Yoon","given":""},{"family":"Silverstein","given":"J."},{"family":"Amy","given":"G."}],"issued":{"date-parts":[["2005"]]}}},{"id":992,"uris":["http://zotero.org/groups/945096/items/HPHVBSWB"],"uri":["http://zotero.org/groups/945096/items/HPHVBSWB"],"itemData":{"id":992,"type":"article-journal","title":"Transport of target anions, chromate (Cr (VI)), arsenate (As (V)), and perchlorate (ClO4), through RO, NF, and UF membranes.","container-title":"Water Science and Technology","page":"327-334","volume":"51","issue":"6-7","author":[{"family":"Yoon","given":"J."},{"family":"Amy","given":"G."},{"family":"Yoon","given":"Y."}],"issued":{"date-parts":[["2005"]]}}},{"id":991,"uris":["http://zotero.org/groups/945096/items/IIJW6E8Q"],"uri":["http://zotero.org/groups/945096/items/IIJW6E8Q"],"itemData":{"id":991,"type":"article-journal","title":"Determination of perchlorate rejection and associated inorganic fouling (scaling) for reverse osmosis and nanofiltration membranes under various operating conditions","container-title":"Journal of Environmental Engineering","page":"726-733","author":[{"family":"Yoon","given":"J."},{"family":"Yoon","given":"Y."},{"family":"Amy","given":"G."},{"family":"Her","given":"N."}],"issued":{"date-parts":[["2005",5]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. While water quality affects process design (e.g., recovery rate, cleaning frequency, and antiscalant selection), it has relatively little effect on perchlorate removal effectiveness of reverse osmosis membranes. Reverse osmosis generates a relatively large concentrate stream, which will contain perchlorate as well as other rejected dissolved solids, which will require disposal. The large concentrate stream also means less treated water is available for distribution (e.g., 70 to 85 percent of source water), which is a disadvantage for systems with limited water supply. Because reverse osmosis can increase the corrosivity of the treated water, it may require post-treatment or blending with bypass water. Reverse osmosis can, however, remove co-occurring contaminants including arsenic and chromium-VI (Amy, Yoon, and Amy, 2005).

B. What are the Small System Compliance Technologies?

The EPA is proposing the SSCT shown in [REF _Ref529958951 \h]. The table shows which of the BAT listed above are also affordable for each small system size category listed in Section 1412(b)(4)(E)(ii) of the SDWA. The Agency identified these technologies based on an analysis of treatment effectiveness and affordability [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"J9AlL73G","properties":{"formattedCitation":"(USEPA, 2018a)","plainCitation":"(USEPA, 2018a)","noteIndex":0},"citationItems":[{"id":1210,"uris":["http://zotero.org/groups/945096/items/QBLZF9AR"],"uri":["http://zotero.org/groups/945096/items/QBLZF9AR"],"itemData":{"id":1210,"type":"article","title":"Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water.","publisher":"EPA ***-*-*-****","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Table X-[SEQ Table * ARABIC \s 1]: Proposed SSCT for Perchlorate Removal

System Size (Population Served)	Ion Exchange	Biological Treatment	Reverse Osmosis	Point-of-Use Reverse Osmosis
25-500	Yes	No	No	Yes
501-3,300	Yes	Yes	Yes	Yes
3,301-10,000	Yes	Yes	Yes	Not applicable[a]

a. For perchlorate, EPA has determined that implementing and maintaining this option for systems larger than 3,300 people (greater than 1 MGD design flow) is likely to be impractical.

The SSCT listed in [REF _Ref529958951 \h] include a point-of-use (POU) version of reverse osmosis in addition to the ion exchange, biological treatment and reverse osmosis technologies described in the previous section. This technology can be used by small systems to comply with the proposed MCL and, therefore, meets the effectiveness requirement for an SSCT. For perchlorate removal, NSF/ANSI Standard 58: Reverse Osmosis Drinking Water Treatment Systems includes a protocol that requires a reverse osmosis unit to be able to reduce perchlorate from a challenge level of 130 µg/L to a target level of 4 µg/L (NSF, 2004). Organizations (e.g., NSF International, Underwriters Laboratories, Water Quality Association) provide third-party testing and certification that POU devices meet drinking water treatment standards. There are no perchlorate certification standards for other types of POU devices such as those using ion exchange media.

The operating principle for POU reverse osmosis devices is the same as centralized reverse osmosis: steric exclusion and electrostatic repulsion of ions from the charged membrane surface. In addition to a reverse osmosis membrane for dissolved ion removal, POU reverse osmosis devices often have a sediment pre-filter and a carbon filter in front of the reverse osmosis membrane, a 3- to 5-gallon treated water storage tank, and a carbon filter between the tank and the tap.

The EPA identified the SSCT using the affordability criteria methodology it developed for drinking water rules [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"LHgBHn5b","properties":{"formattedCitation":"(USEPA, 1998)","plainCitation":"(USEPA, 1998)","noteIndex":0},"citationItems":[{"id":1215,"uris":["http://zotero.org/groups/945096/items/399QNBY4"],"uri":["http://zotero.org/groups/945096/items/399QNBY4"],"itemData":{"id":1215,"type":"article","title":"Variance Technology Findings for Contaminants Regulated Before 1996","publisher":"EPA 815–R– 98–003. September","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["1998"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The analysis method is a comparison of estimated incremental household costs for perchlorate treatment to an expenditure margin, which is the difference between baseline household water costs and a threshold equal to 2.5% of median household income. [REF _Ref529959037 \h] shows the expenditure margins derived for the analysis.

Table X-[SEQ Table * ARABIC \s 1]: Expenditure Margins for SSCT Affordability Analysis

System Size (Population Served)	Median Household Income[a] (a)	Affordability Threshold[b] (b) = 2.5% x a	Baseline Water Cost[c] (c)	Expenditure Margin (d) = b - c
25-500	$52,791	$1,320	$341	$979
501-3,300	$51,093	$1,277	$395	$883
3,301-10,000	$55,975	$1,399	$412	$987

Source: *Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water* [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"2scXqyv0","properties":{"formattedCitation":"(USEPA, 2018a)","plainCitation":"(USEPA, 2018a)","noteIndex":0},"citationItems":[{"id":1210,"uris":["http://zotero.org/groups/945096/items/QBLZF9AR"],"uri":["http://zotero.org/groups/945096/items/QBLZF9AR"],"itemData":{"id":1210,"type":"article","title":"Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water.","publisher":"EPA ***-*-*-****","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

a. MHI based on U.S. Census 2010 American Community Survey (ACS) 5-year estimates [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"x096Tc8Y","properties":{"formattedCitation":"(U.S. Census Bureau, 2010)","plainCitation":"(U.S. Census Bureau, 2010)","noteIndex":0},"citationItems":[{"id":1225,"uris":["http://zotero.org/groups/945096/items/WJ35QNBT"],"uri":["http://zotero.org/groups/945096/items/WJ35QNBT"],"itemData":{"id":1225,"type":"article","title":"American Community Survey, 5-year Estimates (2006-2010)","author":[{"family":"U.S. Census Bureau","given":""}],"issued":{"date-parts":[["2010"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] stated in 2010 dollars, adjusted to 2017 dollars using the CPI (for all items) for areas under 50,000 persons [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"7Rg9m81J","properties":{"formattedCitation":"(Bureau of Labor Statistics (BLS), 2018b)","plainCitation":"(Bureau of Labor Statistics (BLS), 2018b)","noteIndex":0},"citationItems":[{"id":1226,"uris":["http://zotero.org/groups/945096/items/GTI7H6YK"],"uri":["http://zotero.org/groups/945096/items/GTI7H6YK"],"itemData":{"id":1226,"type":"article","title":"CPI--All Urban Consumers (all items), for areas under 50,000 persons","author":[{"family":"Bureau of Labor Statistics (BLS)","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

b. Affordability threshold equals 2.5 percent of MHI.

c. Household water costs derived from 2006 Community Water System Survey [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"fS2lbu6t","properties":{"formattedCitation":"(USEPA, 2009c)","plainCitation":"(USEPA, 2009c)","noteIndex":0},"citationItems":[{"id":163,"uris":["http://zotero.org/groups/945096/items/DZNAAV6M"],"uri":["http://zotero.org/groups/945096/items/DZNAAV6M"],"itemData":{"id":163,"type":"article","title":"2006 Community Water System Survey - Volume II: Detailed Tables and Survey Methodology","URL":"https://www.epa.gov/dwstandardsregulations/community-water-system-survey","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2009",5]]},"accessed":{"date-parts":[["2018",8,17]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], based on residential revenue per connection within each size category, adjusted to 2017 dollars based on the CPI (for all items) for areas under 50,000 persons.

[REF _Ref529959069 \h] shows the estimates of per-household costs by treatment technology and size category generated using the treatment cost method described in section XII.B as well as *Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water* [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"z6GYvRh1","properties":{"formattedCitation":"(USEPA, 2018a)","plainCitation":"(USEPA, 2018a)","noteIndex":0},"citationItems":[{"id":1210,"uris":["http://zotero.org/groups/945096/items/QBLZF9AR"],"uri":["http://zotero.org/groups/945096/items/QBLZF9AR"],"itemData":{"id":1210,"type":"article","title":"Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water.","publisher":"EPA ***-*-*-****","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] and *Technologies and Costs for Treating Perchlorate-Contaminated Waters* [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"18aKvRLD","properties":{"formattedCitation":"(USEPA, 2018f)","plainCitation":"(USEPA, 2018f)","noteIndex":0},"citationItems":[{"id":147,"uris":["http://zotero.org/groups/945096/items/VUJUPN7L"],"uri":["http://zotero.org/groups/945096/items/VUJUPN7L"],"itemData":{"id":147,"type":"article","title":"Technologies and Costs for Treating Perchlorate-Contaminated Waters","publisher":"EPA ***-*-*-****","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Costs in bold font do not exceed the corresponding expenditure margin and, therefore, meet the SSCT affordability criterion. Therefore, the EPA has determined that there are affordable small system compliance technologies available and the Agency is not proposing any variance technologies.

Table X-[SEQ Table * ARABIC \s 1]: Annual Incremental Cost Estimates for SSCT Affordability Analysis

System Size (Population Served)	Ion Exchange	Biological Treatment	Reverse Osmosis	Point-of-Use Reverse Osmosis
25-500	**$378 to $610**	$2,146 to $3,709	$2,272 to $2,671	**$265 to $271**
501-3,300	**$98 to $148**	**$324 to $566**	**$561 to $688**	**$250 to $251**
3,301-10,000	**$104 to $153**	**$211 to $315**	**$431 to $493**	Not applicable[a]

Source: *Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water* [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"8y1WSJT4","properties":{"formattedCitation":"(USEPA, 2018a)","plainCitation":"(USEPA, 2018a)","noteIndex":0},"citationItems":[{"id":1210,"uris":["http://zotero.org/groups/945096/items/QBLZF9AR"],"uri":["http://zotero.org/groups/945096/items/QBLZF9AR"],"itemData":{"id":1210,"type":"article","title":"Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water.","publisher":"EPA ***-*-*-****","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], which describes the different WBS model input assumptions that result in ranges of per-household costs shown; bold font indicates cost estimates that do not exceed the corresponding expenditure margin.

a. For perchlorate, EPA has determined that implementing and maintaining a POU program for systems larger than 3,300 people (greater than 1 MGD design flow) is likely to be impractical.

XI. Rule Implementation and Enforcement

A. What are the Requirements for Primacy?

This section describes the regulations and other procedures and policies primacy entities must adopt, or have in place, to implement the proposed perchlorate rule. States must continue to meet all other conditions of primacy in 40 CFR part 142. Section 1413 of the SDWA establishes requirements that primacy entities (States or Indian Tribes) must meet to maintain primary enforcement responsibility (primacy) for its public water systems. These include: (1) Adopting drinking water regulations that are no less stringent than federal NPDWRs in effect under sections 1412(a) and 1412(b) of the Act, (2) Adopting and implementing adequate procedures for enforcement, (3) Keeping records and making reports available on activities that the EPA requires by regulation, (4) Issuing variances and exemptions (if allowed by the State) under conditions no less stringent than allowed by SDWA sections 1415 and 1416, and (5) Adopting and being capable of implementing an adequate plan for the provision of safe drinking water under emergency situations.

40 CFR part 142 sets out the specific program implementation requirements for States to obtain primacy for the Public Water Supply Supervision Program, as authorized under section 1413 of the Act.

To implement the perchlorate rule, States would be required to adopt revisions at least as stringent as the proposed provisions in 40 CFR 141.6 (Effective Dates); 40 CFR 141.23 (Inorganic chemical sampling and analytical requirements); 40 CFR 141.51 (Maximum contaminant level goals for inorganic contaminants); 40 CFR 141.60 (Effective Dates); 40 CFR 141.62 (Maximum contaminant levels for inorganic contaminants); Appendix A to Subpart O ([Consumer Confidence Report] Regulated contaminants); Appendix A to Subpart Q (NPDWR violations and other situations requiring public notice); Appendix B to Subpart Q (Standard health effects language for public notification); and 40 CFR 142.62 (Variances and exemptions from the maximum contaminant levels for organic and inorganic contaminants). Under 40 CFR 142.12(b), all primacy States/territories/tribes would be required to submit a revised program to the EPA for approval within two years of promulgation of any final perchlorate NPDWR or could request an extension of up to two years in certain circumstances.

B. What are the State Record Keeping Requirements?

The current regulations in 40 CFR 142.14 require States with primary enforcement responsibility (i.e., primacy) to keep records of analytical results to determine compliance, system inventories, sanitary surveys, State approvals, vulnerability and waiver determinations, monitoring requirements, monitoring frequency decisions, enforcement actions, and the issuance of variances and exemptions. The State record keeping requirements remain unchanged and would apply to perchlorate as with any other regulated contaminant.

C. What are the State Reporting Requirements?

Currently, States must report to the EPA information under 40 CFR 142.15 regarding violations, variances and exemptions, enforcement actions and general operations of State public water supply programs. The State reporting requirements remain unchanged and would apply to perchlorate as with any other regulated contaminant.

XII. Health Risk Reduction Cost Analysis

Section 1412(b)(3)(C) of the 1996 Amendments to the SDWA requires the EPA to prepare a Health Risk Reduction and Cost Analysis (HRRCA) in support of any NPDWR that includes an MCL. This section addresses the HRRCA requirements as indicated:

- Quantifiable and non-quantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level (Sections XII.C and XII.D);
- Quantifiable and non-quantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the MCL, excluding benefits resulting from compliance with other proposed or promulgated regulations (Section XII.C);
- Quantifiable and non-quantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the MCL, including monitoring, treatment, and other costs, and excluding costs resulting from compliance with other proposed or promulgated regulations (Section XII.B and XII.D);

- The incremental costs and benefits associated with each alternative MCL considered (Section XII.D);
- The effects of the contaminant on the general population and on groups within the general population, such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other sensitive populations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population (Section XII.C and Section III);
- Any increased health risk that may occur as the result of compliance, including risks associated with co-occurring contaminants (Section XII.C); and
- Other relevant factors, including the quality and extent of the information, the uncertainties in the analysis, and factors with respect to the degree and nature of the risk (Section XII.E).

A. Identifying Affected Entities

If EPA issues a final NPDWR for perchlorate, it would affect the following entities: CWSs and NTNCWSs that must meet the proposed MCL and monitoring and reporting requirements; and primacy agencies that must adopt and enforce the MCL as well as the monitoring and reporting requirements. All of these entities would incur costs, including administrative costs, monitoring and reporting costs, and – in a limited number of cases – costs to reduce perchlorate levels in drinking water to meet the proposed MCL using treatment or nontreatment options. Section B describes the method the EPA used to estimate these costs.

The systems that reduce perchlorate concentrations will reduce associated health risks. The EPA developed a method to estimate the potential benefits of reduced perchlorate exposure among the service populations of systems with elevated baseline perchlorate levels. Section XII.C describes this method.

Section XII.D provides the cost and benefit estimates. The EPA prepared the Health Risk Reduction Cost Analysis of the Proposed Perchlorate Rule (USEPA, 2018b), which is available in the docket for the proposed rule. Section XII.E summarizes and discusses key uncertainties in the cost and benefit analyses.

B. Method for Estimating Costs

The EPA estimated costs for CWS and NTNCWS to monitor and report and estimated the costs for a subset of public water systems with perchlorate levels greater than the proposed MCL to install and operate treatment. The EPA assumed that affected water systems would adopt ion exchange treatment although other treatment or nontreatment options may be lower cost or help achieve other water system objectives. EPA also estimated the costs for States and other primacy agencies to assure systems implement the rule and to report information to the EPA.

The EPA estimated initial costs for all CWS and NTNCWS operators to read and understand the rule and provide training to their staff to implement the proposed rule. The EPA also estimated the recurring costs for all CWS and NTNCWS operators to conduct monitoring, report results, and apply for waivers. Table XII-1 summarizes the frequency and labor hour assumptions for this analysis.

Table XII-1: Labor Hours for Drinking Water Systems Administrative and Monitoring Requirements

Activity	Frequency	Small System Hours	Large System Hours
Read the rule	one time per system	4	4
Provide initial training	one time per system	16	32
Apply to State for monitoring waiver	once every 9 years per eligible system	16	16
Collect a single finished water sample[1]	per monitoring event	1	1

Source (USEPA, 2000a). The EPA's cost analysis reflects full MCL compliance and therefore the EPA did not estimate Tier 1 notification costs.
1. The estimate is per sample. Therefore, a system conducting a year of quarterly monitoring at three entry points incurs a total of 12 hours of labor to complete the task (3 entry points x 4 samples x 1 hour per sample).

To estimate costs to CWSs and NTNCWSs associated with compliance monitoring and other administrative costs, the EPA generally uses the labor rate[12] for full-time treatment plant operators in CWSs from USEPA [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"5g8IJ6Eh","properties":{"formattedCitation":"(2011)","plainCitation":"(2011)","noteIndex":0},"citationItems":[{"id":992,"uris":["http://zotero.org/groups/945096/items/FHCVSMRC"],"uri":["http://zotero.org/groups/945096/items/FHCVSMRC"],"itemData":{"id":992,"type":"article","title":"Labor Cost for National Drinking Water Rules","author":[{"family":"USEPA","given":""}],"issued":{"date-

[12] Updated to 2017$ using the BLS Employment Cost Index for Total Compensation for Private industry workers in Utilities.

parts":[["2011"]]}},"suppress-author":true}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], which vary based on the size of the system. The EPA calculated a weighted average fully loaded hourly wage rate for water systems of $34.71.

Additionally, the EPA assumed that systems will incur an average analytical cost of $64 per sample, which is the average cost per sample obtained from multiple laboratories for perchlorate quantitation using Method 314.0.

To estimate treatment cost, the EPA utilized the occurrence data described in Section VI to estimate the number of systems that currently have perchlorate at concentrations exceeding the proposed and alternative MCLs. The EPA estimated costs that those water systems would incur to install and maintain treatment using its work breakdown structure (WBS) cost estimating models. The WBS models are spreadsheet-based engineering models for individual treatment technologies, linked to a central database of component unit costs. The WBS approach involves breaking a process down into discrete components for the purpose of estimating costs and produce a comprehensive assessment of the capital and operating requirements for a treatment system[13]. The EPA used the WBS models to generate total capital and O&M cost estimates for each technology and nontreatment option for up to 49 different system flow rates. The EPA

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[13] The document *Technologies and Costs for Treating Perchlorate-Contaminated Waters* (USEPA, 2018d) contains more complete discussion of the WBS models and the cost estimating approach.

generated separate estimates that correspond to different water sources (groundwater or surface water), three different cost levels (low, mid, and high), and different technology-specific scenarios (e.g., 105,000 or 170,000 bed volumes for ion exchange). The EPA used the mid-cost estimates for ion exchange to generate expected costs for all entry points requiring perchlorate removal. This technology cost-effectively removes perchlorate, but its ability to remove co-occurring contaminants depends on influent characteristics and process design. Therefore, EPA did not assume that treatment might result in ancillary quantifiable or non-quantifiable benefits of removing co-occurring ions such as nitrate. Treatment costs include waste disposal for spent resin, but do not include post-treatment costs for corrosion control because blending rates at most entry points should not result in much chloride addition or changes in corrosivity.

For purposes of estimating the costs and benefits, the EPA assumed that CWSs and NTNCWSs in California and Massachusetts would not incur additional cost or realize benefits because these States currently regulate perchlorate at a more stringent level than the proposed MCL and alternative MCL. For each entry point in the UCMR 1 dataset outside of these two States, the EPA compared the maximum observed perchlorate concentration to the MCL to identify those that have an exceedance of the proposed MCL. The EPA assumed that these entry points would incur costs for an additional confirmation sample and would need to implement treatment to meet the MCL. For each entry point, the EPA estimated the design flow and the average flow by service populations based on the Agency's prior analysis of the relationships between these values (USEPA, 2000b). The Agency assumed blending of treated water and untreated water would be used to meet an average treatment target equal to 80 percent of the MCL (for an MCL of 56 μg/L the blending target would be 45 μg/L) given a 95 percent removal effectiveness until perchlorate breakthrough. The Agency applied the capital cost and O&M cost curves from the WBS models to the design and average flows adjusted for blending. When small systems in the UCMR 1 sample incurred treatment costs, the EPA extrapolated the costs on a per capita basis to the estimate of national population exposure derived using the small system population sampling weights.

For the primacy agencies that will implement and enforce the rule (including 49 States, one tribal nation and 5 territories), the EPA estimated upfront costs incurred during the three years between rule promulgation and the effective date to read and understand the rule, adopt regulatory changes, and provide training to CWSs and NTNCWSs and agency staff. Primacy agencies will also have recurring costs to review waiver applications and monitoring reports. Table XII-2 summarizes the labor hour assumptions for these activities.

Table XII-2: Labor Hours for Primacy Agency Administrative Requirements

Activity	Frequency	Hours
Read and understand the rule, adopt regulatory changes[1]	one time per Agency	416
Provide initial training and assistance to water systems[2]	total per Agency	2,080
Provide initial training to staff[2]	total per Agency	250
Review waiver applications	once every 9 years per eligible system	8
Review monitoring reports	per monitoring event	1

Source (USEPA, 2000a)

1. The EPA assumed that two States that already regulate perchlorate in drinking water would not incur the incremental burdens in this table to regulate perchlorate under the proposed rule because they already incur baseline costs for perchlorate regulation including monitoring costs. The Agency assumed, however, that the two States would incur an average of 40 hours to confirm that their existing requirements are at least as protective as the proposed rule.
2. The EPA assumed that all training hours occur in a single year, although the hours may actually occur over time. The total hour estimates are average values across States.

State labor rates are based on the mean hourly wage rate from Bureau of Labor Statistics (BLS) Standard Occupational Classification code 19-2041 (State Government –Environmental Scientists and Specialists, Including Health). Wages are loaded using a factor calculated from the BLS Employer Costs for Employee Compensation report [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"C1A8zUkj","properties":{"formattedCitation":"(Bureau of Labor Statistics (BLS), 2016 Table 3)","plainCitation":"(Bureau of Labor Statistics (BLS), 2016 Table 3)","noteIndex":0},"citationItems":[{"id":984,"uris":["http://zotero.org/groups/945096/items/L8X3BDZ9"],"uri":["http://zotero.org/groups/945096/items/L8X3BDZ9"],"itemData":{"id":984,"type":"webpage","title":"Employer Cost for Employee Compensation -- September 2016","author":[{"literal":"Bureau of Labor Statistics (BLS)"}],"issued":{"date-parts":[["2016"]]}},"label":"book","suffix":"Table 3"}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], for a fully loaded hourly wage rate for States of $50.67.

The proposed rule provides three years between the effective dates and compliance dates for systems. For the purpose of estimating costs, the EPA assumed that large CWSs would phase in administrative costs, including initial monitoring, and upfront administrative costs uniformly over the 3 years following the effective date (i.e., years 4 to 6 of the analysis period). Similarly, the EPA assumed that small CWSs and NTNCSs will phase in these costs over the subsequent three-year period (i.e., years 7 to 9 of the analysis period). The EPA assumed that, within these periods, all systems would conduct initial monitoring – one year of quarterly monitoring to determine whether perchlorate concentrations are consistently and reliably below the proposed MCL. Thereafter, systems with MCL exceedances would continue to monitor quarterly, while systems below the MCL that obtain waivers will monitor annually for three years (surface water systems) or triennially for 9 years (ground water systems), then incur costs for a waiver application. Thereafter, these systems will continue reduced monitoring - once every nine years - under subsequent waivers. Systems that are below the MCL without waivers will monitor once per year (surface water systems) or once every three years (groundwater). Consistent with [

ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"mnzEXxZK","properties":{"formattedCitation":"(USEPA, 2008b)","plainCitation":"(USEPA, 2008b)","dontUpdate":true,"noteIndex":0},"citationItems":[{"id":998,"uris":["http://zotero.org/groups/945096/items/QSXYHBID"],"uri":["http://zotero.org/groups/945096/items/QSXYHBID"],"itemData":{"id":998,"type":"article","title":"Draft Information Collection Request for the Disinfectants/Disinfection Byproducts, Chemical, and Radionuclides Rule","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2008",6]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}], the EPA assumed that 90% of groundwater and 40% of surface water systems that have all entry points below the MCL would obtain waivers.

The EPA estimated the costs over a 35-year analysis period, which includes a 3-year period prior to the effective date to allow for State rule adoption activities, a 3-year period after the effective date to allow initial monitoring among large CWSs, and a 3-year period after that to allow initial monitoring for small CWSs and NTNCWSs. Evaluating costs over 35 years covers a full life cycle of the capital investments that large systems make in the 6th year; the WBS estimates of composite useful life of the equipment and infrastructure investment is approximately 30 years. The EPA assumed that treatment modifications will be completed in the final year of the initial monitoring period (i.e., year 6 of the analysis for large CWSs and year 9 for small CWSs and NTNCWSs). The EPA calculated the present value of total costs in each year of the analysis period and discounted to year 1 using both a 3% and 7% discount rate and annualized total present value of costs at the same rates over 35 years to obtain a constant total annual cost estimate to compare to total annual benefits.

Water systems typically recover costs through increased household rates, resulting in increased costs at the household level[14]. To calculate the magnitude of the cost increase for systems that exceed the proposed MCL or alternative MCL, the EPA first estimated the number of households that may incur costs as a result of the rule based on the population served by affected CWSs and NTNCWSs and the average household size [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"Q6RKolIZ","properties":{"formattedCitation":"(U.S. Census Bureau, 2017b)","plainCitation":"(U.S. Census Bureau, 2017b)","noteIndex":0},"citationItems":[{"id":1000,"uris":["http://zotero.org/groups/945096/items/CGU3LT9N"],"uri":["http://zotero.org/groups/945096/items/CGU3LT9N"],"itemData":{"id":1000,"type":"article","title":"Average Household Size of Occupied Housing Units by Tenure. American Community Survey 1-Year Estimates: Table B25010","author":[{"family":"U.S. Census Bureau","given":""}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The EPA divided the total annual system-level costs by the number of households served by the system.

[14] For systems with monitoring costs only, household-level costs will be negligible.

C. *Method for Estimating Benefits*

The EPA has taken an approach in evaluating the benefits for perchlorate that is consistent with the SAB's recommendations for the methodology to inform the MCLG for perchlorate. This approach involves a) using a BBDR model to estimate the impact of perchlorate on maternal thyroid hormone levels during the first trimester of pregnancy, and b) using a dose-response function from the epidemiological literature to model the relationship between altered maternal thyroid hormone levels and offspring IQ. Currently available science has limited this quantitative benefits assessment to quantifying the relationship between perchlorate and IQ. Given that alterations in thyroid hormones have been associated with other adverse outcomes, including reproductive outcomes (Alexander et al., 2017; Hou et al., 2016; Maraka et al., 2016) and effects on cardiovascular systems (Asvold et al., 2012; Sun et al., 2017) there are likely non-quantified benefits of risk reductions for other endpoints or reduced exposure to co-occurring contaminants, which are addressed below. Uncertainties regarding the quantifiable benefits are also addressed below.

The population impacted by the rule for which benefits can be quantified is specific to live births from mothers who were served by a CWS or NTNCWS with perchlorate concentrations above the potential MCLs. To determine the nationwide population of children that will experience a quantifiable benefit of avoided IQ decrements from reducing maternal perchlorate exposure during pregnancy, the EPA first estimated the total population being served by systems above the MCL based on data from UCMR 1. The EPA then multiplied the total population served for each affected CWS and NTNCWS by the proportion of women of childbearing age (aged 15-44) in the US, which is 19.7 percent [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"rCNbGglo","properties":{"formattedCitation":"(U.S. Census Bureau, 2017a)","plainCitation":"(U.S. Census Bureau, 2017a)","noteIndex":0},"citationItems":[{"id":189,"uris":["http://zotero.org/groups/945096/items/ZM7S6H44"],"uri":["http://zotero.org/groups/945096/items/ZM7S6H44"],"itemData":{"id":189,"type":"article","title":"Annual estimates of the resident population by single year of age and sex for the United States: April 1, 2010 to July 1, 2016.","URL":"https://www.census.gov/data/datasets/2016/demo/popest/nation-detail.html#ds","author":[{"literal":"U.S. Census Bureau"}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. The number of women of child-bearing age for each entry point was then multiplied by the annual number of live births in the US, or 62 births per 1,000 women (6.2 percent) [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"7XfZyKhY","properties":{"formattedCitation":"(Martin, Hamilton, & Osterman, 2017)","plainCitation":"(Martin, Hamilton, & Osterman, 2017)","noteIndex":0},"citationItems":[{"id":186,"uris":["http://zotero.org/groups/945096/items/MY6LPDKD"],"uri":["http://zotero.org/groups/945096/items/MY6LPDKD"],"itemData":{"id":186,"type":"article","title":"Births in the United States, 2016. NCHS Data Brief No. 287","URL":"https://www.cdc.gov/nchs/data/databriefs/db287.pdf","author":[{"family":"Martin"

,"given":"J.A."},{"family":"Hamilton","given":"B.E."},{"family":"Osterman","given":"M.J.K"}],"issued":{"date-parts":[["2017"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

The EPA used a two-step dose-response model to estimate health benefits of a reduction in perchlorate exposure as a result of regulating perchlorate in drinking water not to exceed the proposed MCL of 56 µg/L and alternative ~~MCL~~MCLs of 18 µg/L and 90 µg/L. The first step relates changes in perchlorate to changes in maternal free-thyroxine (fT4) during the first trimester of pregnancy using the EPA's BBDR model. Because the dose-response relationship between perchlorate exposure and maternal fT4 is dependent on maternal iodine intake status, this first-step analysis is repeated for several categories of iodine intake.

The second step of the dose-response model subsequently relates the predicted changes in maternal fT4 from the BBDR model to changes in child IQ using the function estimated in the EPA independent analysis of the [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"iqyVRL6z","properties":{"formattedCitation":"(Korevaar et al., 2016)","plainCitation":"(Korevaar et al., 2016)","dontUpdate":true,"noteIndex":0},"citationItems":[{"id":43,"uris":["http://zotero.org/groups/945096/items/B968J6XI"],"uri":["http://zotero.org/groups/945096/items/B968J6XI"],"itemData":{"id":43,"type":"article-journal","title":"Association of maternal thyroid function during early pregnancy with offspring IQ and brain morphology in childhood: a population-based prospective cohort study","container-title":"The Lancet Diabetes & Endocrinology","page":"35-

43","volume":"4","issue":"1","source":"ScienceDirect","abstract":"SummaryBackground\nThyroid hormone is involved in the regulation of early brain development. Since the fetal thyroid gland is not fully functional until week 18–20 of pregnancy, neuronal migration and other crucial early stages of intrauterine brain development largely depend on the supply of maternal thyroid hormone. Current clinical practice mostly focuses on preventing the negative consequences of low thyroid hormone concentrations, but data from animal studies have shown that both low and high concentrations of thyroid hormone have negative effects on offspring brain development. We aimed to investigate the association of maternal thyroid function with child intelligence quotient (IQ) and brain morphology.\nMethods\nIn this population-based prospective cohort study, embedded within the Generation R Study (Rotterdam, Netherlands), we investigated the association of maternal thyroid function with child IQ (assessed by non-verbal intelligence tests) and brain morphology (assessed on brain MRI scans). Eligible women were those living in the study area at their delivery date, which had to be between April 1, 2002, and Jan 1, 2006. For this study, women with available serum samples who presented in early pregnancy (<18 weeks) were included. Data for maternal thyroid-stimulating hormone, free thyroxine, thyroid peroxidase antibodies (at weeks 9–18 of pregnancy), and child IQ (assessed at a median of 6·0 years of age [95% range 5·6–7·9 years]) or brain MRI scans (done at a median of 8·0 years of age [6·2–10·0]) were obtained. Analyses were adjusted for potential confounders including concentrations of human chorionic gonadotropin and child thyroid-stimulating hormone and free thyroxine.\nFindings\nData for child IQ were available for 3839 mother–child pairs, and MRI scans were available from 646 children. Maternal free thyroxine concentrations showed an inverted U-shaped association with child IQ (p=0·0044), child grey matter volume (p=0·0062), and cortex volume (p=0·0011). For both low and high maternal free thyroxine concentrations, this association corresponded to a 1·4–3·8 points reduction in mean child IQ. Maternal thyroid-stimulating hormone was not associated with child IQ or brain morphology. All associations remained similar after the exclusion of women with overt hypothyroidism and overt hyperthyroidism, and after adjustment for concentrations of human chorionic gonadotropin, child thyroid-stimulating hormone and free thyroxine or thyroid peroxidase antibodies (continuous or positivity).\nInterpretation\nBoth low and high maternal free thyroxine concentrations during pregnancy were associated with lower child IQ and lower grey matter and cortex volume. The association between high maternal free thyroxine and low child IQ suggests that levothyroxine therapy during pregnancy, which is often initiated in women with subclinical hypothyroidism during pregnancy, might carry the potential risk of adverse child neurodevelopment outcomes when the aim of treatment is to achieve high-normal thyroid function test results.\nFunding\nThe Netherlands Organisation for Health Research and Development (ZonMw) and the European Community's Seventh Framework Programme.","DOI":"10.1016/S2213-8587(15)00327-7","ISSN":"2213-8587","shortTitle":"Association of maternal thyroid function during early pregnancy with offspring IQ and brain morphology in childhood","journalAbbreviation":"The Lancet Diabetes & Endocrinology","author":[{"family":"Korevaar","given":"Tim I M"},{"family":"Muetzel","given":"Ryan"},{"family":"Medici","given":"Marco"},{"family":"Ch aker","given":"Layal"},{"family":"Jaddoe","given":"Vincent W V"},{"family":"Rijke","given":"Yolanda B","non-dropping-particle":"de"},{"family":"Steegers","given":"Eric A P"},{"family":"Visser","given":"Theo J"},{"family":"White","given":"Tonya"},{"family":"Tiemeier","given":"Henning"},{"family":"Peeters","given":"Robin P"}],"issued":{"date-parts":[["2016",1]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] study data. Ultimately, the changes in IQ are estimated for each iodine intake group, and all of the iodine intake groups' IQ decrements are averaged together based on the proportion of individuals in each iodine intake category. Table XII-3 shows the specific iodine intake groups and the proportion of non-pregnant women of childbearing age that fall into each group.

Table XII-3: Proportion of Population based on Maternal Iodine Intake Status

Iodine Intake Range (µg/ day) used for Benefits Analysis	Proportion of the population
0 to <55	7.14%
55 to <60	2.15%
60 to <65	1.06%
65 to < 70	1.86%
70 to <75	1.31%
75 to <80	3.10%
80 to <85	2.62%
85 to <90	1.20%
90 to <95	1.83%
95 to <100	2.94%
100 to <125	13.56%
125 to <150	9.08%
150 to <170	10.31%
170 to <300	24.47%
≥300	17.36%

Source: U.S. EPA (2018b).

These changes in child IQ are then monetized using the EPA's estimate of the value of an IQ point. This estimate reflects the discounted present value of lifetime income reductions attributable to a 1-point reduction in IQ at birth. Therefore, the present value depends on the discount rate. At a 3 percent discount rate, the estimate is $18,686 per IQ point; at a 7 percent discount rate the estimate is $3,631.

Other potential benefits not quantified or monetized include additional avoided health effects which cannot currently be monetized, improved public perception of water quality, as well as a possible reduction of other co-occurring contaminants as a result of water treatment for removal of perchlorate. For example, all of the treatment technologies evaluated for this rule (ion exchange, biological treatment, and reverse osmosis) can also remove co-occurring nitrate from drinking water. Section XII-E provides additional discussion of uncertainties in this analysis.

D. Comparison of Costs and Benefits

This section provides the estimates of costs and benefits that the EPA derived using the methods described above. It includes estimates for the proposed and alternative MCLs.

For the proposed MCL of 56 µg/L, Table XII-4 summarizes the total cost of the proposed rule to water systems and primacy agencies, and Table XII-5 summarizes the per-household cost for the system incurring treatment costs[15]. Table XII-6 summarizes the quantified benefits. In both instances, the estimates based on the UCMR 1 sample are also national estimates because treatment costs occur only at large systems; there are no small system treatment costs or related benefits to extrapolate.

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[15] For all households served by all of the systems subject to the monitoring costs as well as MCL compliance, the average annual cost is less than $0.20.

Table XII-4: Summary of Total Annualized Costs at MCL of 56 μg/L (Millions; 2017$)

Cost Component	3% Discount	7% Discount
Drinking Water Systems Treatment Costs	$0.65	$0.70
Drinking Water Systems Monitoring and Administration Costs[1]	$5.93	$6.38
Drinking Water Systems Costs Subtotal	$6.58	$7.07
State Administration Costs	$3.09	$3.20
Total Costs	$9.67	$10.28

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"00m0B8b8","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Detail may not sum to total because of independent rounding.

1. Costs include monitoring for all CWS and NTNCWS. Some consecutive systems that purchase 100% of their water from wholesale systems may not be required to monitor for perchlorate provided States allow integrated system agreements to include perchlorate among the monitoring requirements that the wholesale system fulfills for the consecutive system. The potential number of consecutive systems excluded from perchlorate monitoring depends on system and State decisions and, therefore, is unknown. Excluding monitoring costs for approximately 8,400 consecutive systems that do not report a water source facility (e.g., well or intake) in SDWIS/FED from the monitoring cost analysis reduces annualized monitoring costs by $0.8 million.

Table XII-5: Summary of Household-Level Annual Costs for Systems Treating to Comply with MCL at 56 μg/L (2017$)

Cost Range	3% Discount	7% Discount
Minimum	$11	$14
Average	$40	$47
Maximum	$69	$80

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"xTqTuaNv","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

Table XII-6: Summary of Total Annualized Benefits of Avoided Lost IQ Decrements at MCL of 56 μg/L (Millions; 2017$)

Korevaar β distribution	Annual Delta IQ	3% Discount	7% Discount
Upper	243	$3.57	$0.60
Central	136	$2.00	$0.34
Lower	30	$0.44	$0.07

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"T7LDdiyn","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

For the alternative MCL of 18 μg/L, Table XII-7 summarizes the total cost of the proposed rule to water systems and primacy agencies, and Table XII-8 summarizes the per-household cost for systems requiring treatment, which vary across the systems. Table XII-9 summarizes the quantified benefits. At this threshold, one entry point for one small system in the UCMR 1 data had an exceedance. Therefore, the EPA extrapolated the treatment costs and benefits from the UCMR 1 estimates to national estimates based on sampling weights.

Table XII-7: Summary of Total Annualized Costs at MCL of 18 μg/L (Millions; 2017$)

Cost Component	3% Discount (UCMR 1)[1]	7% Discount (UCMR 1)[1]	3% Discount (National)[1]	7% Discount (National)[1]
Drinking Water Systems Treatment Costs	$6.92	$7.29	$7.92	$8.37
Drinking Water Systems Monitoring and Administration Costs	$5.94	$6.38	$5.94	$6.38
Drinking Water Systems Costs Subtotal	$12.85	$13.67	$13.86	$14.75
State Administration Costs	$3.09	$3.21	$3.09	$3.21
Total Costs	$15.95	$16.88	$16.95	$17.96

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"H6Rcd4Hf","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Detail may not sum to total because of independent rounding.

1. The EPA applied statistical sampling weights to the results to extrapolate small system results to national results. The entry point at which a measurement exceeds 18 μg/L is one of 20 in its sample stratum; no other sample in the stratum had a measurement of perchlorate greater than the minimum reporting level. The entry point population of 2,155 represents 5.31% of the total population served by the six UCMR 1 systems in the stratum (40,574). Currently, the stratum population of 775,000 accounts for 1.32% of the 58.7 million national population served by small systems. Thus, the UCMR 1 results indicate that 0.07% (5.31% x 1.32%) of small system customers (approximately 41,100) may be exposed to perchlorate greater than 18 μg/L. The EPA calculated per-capita costs for the system and extrapolated to national level based on this population estimate.
2. Costs include monitoring for all CWS and NTNCWS. Under 40 CFR 141.29 some consecutive systems that purchase 100% of their water from wholesale systems may not be required to monitor for perchlorate provided primacy agencies, with EPA concurrence, allow integrated system agreements to include perchlorate among the monitoring requirements that the wholesale system fulfills for the consecutive system. The potential number of consecutive systems excluded from perchlorate monitoring depends on system and primacy agency decisions and, therefore, is unknown. Excluding monitoring costs for approximately 8,400 consecutive systems that do not report a water source facility (e.g., well or intake) in SDWIS/FED from the monitoring cost analysis reduces annualized monitoring costs by $0.8 million.

Table XII-8: Summary of Household-Level Annual Costs for Systems Treating to Comply with the MCL at 18 µg/L (2017$)

Cost Range	3% Discount (UCMR 1)[1]	7% Discount (UCMR 1)[1]	3% Discount (National)[1]	7% Discount (National)[1]
Minimum	$18	$24	$18	$24
Average	$38	$46	$38	$46
Max	$72	$84	$72	$84

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"uu13kmuC","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

1. National cost estimates include extrapolation for one small system entry point to national estimates based on sampling weights. The per-household costs are the same for the sample and national extrapolations because the small system cost extrapolation occurs on a per-capita basis.

Table XII-9: Total and Annualized Benefits of Avoided Lost IQ Decrements at 18 µg/L (Millions; 2017$)

Korevaar β distribution	Annual Delta IQ		UCMR 1		National[1]	
	UCMR 1	National[1]	3% Discount	7% Discount	3% Discount	7% Discount
Upper	442	447	$6.50	$1.10	$6.56	$1.11
Central	248	251	$3.65	$0.62	$3.68	$0.62
Lower	54	55	$0.80	$0.13	$0.80	$0.14

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"EN9pibZj","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

1. EPA applied statistical sampling weights to the results to extrapolate small system results to national results. The entry point at which a measurement exceeds 18 µg/L is one of 20 in its sample stratum; no other sample in the stratum had a measurement of perchlorate greater than the minimum reporting level. The entry point population of 2,155 represents 5.31% of the total population served by the six UCMR 1 systems in the stratum (40,574). Currently, the stratum population of 774,780 accounts for 1.32% of the 58.7 million national population served by small systems. Thus, the UCMR 1 results indicate that 0.07% (5.31% x 1.32%) of small system customers (approximately 41,100) may be exposed to perchlorate greater than 18 µg/L. The EPA assumed that this population would incur benefits equivalent to the sampled entry point's population.

For the alternative MCL of 90 µg/L, Table XII-10 summarizes the total cost of the proposed rule to water systems and primacy agencies, and Table XII-11 summarizes the per-household cost for systems requiring treatment, which vary across the systems. Table XII-12 summarizes the quantified benefits. At this threshold, no small systems in the UCMR 1 data had an exceedance. Therefore, treatment costs and benefits for the UCMR 1 data are the national estimates.

Table XII-10: Summary of Total Annualized Costs at MCL of 90 µg/L (Millions; 2017$)

Cost Component	3% Discount	7% Discount
Drinking Water Systems Treatment Costs	$0.49	$0.52
Drinking Water Systems Monitoring and Administration Costs[1]	$5.93	$6.37
Drinking Water Systems Costs Subtotal	$6.42	$6.89
State Administration Costs	$3.09	$3.20
Total Costs	$9.51	$10.10

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"00m0B8b8","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Detail may not sum to total because of independent rounding.

1. Costs include monitoring for all CWS and NTNCWS. Some consecutive systems that purchase 100% of their water from wholesale systems may not be required to monitor for perchlorate provided States allow integrated system agreements to include perchlorate among the monitoring requirements that the wholesale system fulfills for the consecutive system. The potential number of consecutive systems excluded from perchlorate monitoring depends on system and State decisions and, therefore, is unknown. Excluding monitoring costs for approximately 8,400 consecutive systems that do not report a water source facility (e.g., well or intake) in SDWIS/FED from the monitoring cost analysis reduces annualized monitoring costs by $0.8 million.

Table XII-11: Summary of Household-Level Annual Costs for Systems Treating to Comply with MCL at 90 µg/L (2017$)

Cost Range	3% Discount	7% Discount
Minimum	$65	$76
Average	$65	$76
Maximum	$65	$76

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Table XII-12: Summary of Total Annualized Benefits of Avoided Lost IQ Decrements at MCL of 90 µg/L (Millions; 2017$)

Korevaar β distribution	Annual Delta IQ	3% Discount	7% Discount
Upper	222	$3.26	$0.55
Central	124	$1.83	$0.31
Lower	27	$0.40	$0.07

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"T7LDdiyn","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]

Table XII-13 provides a comparison of benefits and costs for ~~both~~three MCL values. First, the table shows the total annual costs and total annual benefits for each MCL. In ~~either case~~all cases, the total costs are substantially higher than the potential range of quantifiable benefits. The table also shows the incremental impact on costs and benefits between ~~and~~an MCL of 56 µg/L and an MCL of 18 µg/L and between an MCL of 90 µg/L and 56 µg/L.

The infrequent occurrence of perchlorate at levels of health concern imposes high monitoring and administrative cost burdens on public water systems and the States. Based on a comparison of costs and benefits estimated at the proposed MCL of 56 µg/L using the best available science and data, the EPA Administrator has determined that the benefits of establishing an NPDWR for perchlorate do not justify the associated costs. In addition, the Administrator also finds that the benefits of an NPDWR at the alternative MCL values of 18 ~~ug~~μg/L and 90 μg/L do not justify the resulting rule costs.

Table XII-~~10~~13: Comparison of Annual Costs and Benefits by MCL (Millions; 2017$)

MCL Value	Cost 3% Discount	Benefit 3% Discount	Cost 7% Discount	Benefit 7% Discount
UCMR 1				
90 μg/L	$9.51	$0.40 - $3.26	$10.10	$0.07 - $0.55
56 μg/L	$9.67	$0.44 - $3.57	$10.28	$0.07 - $0.60
18 μg/L	$15.95	$0.80 - $6.50	$16.88	$0.13 - $1.10
Incremental (from 90 μg/L to 56 μg/L)	$0.16	$0.04 - $0.31	$0.18	$0.0 – 0.05
Incremental (from 56 μg/L to 18 μg/L)	$6.28	$0.36 - $2.93	$6.60	$0.06 - $0.50
National				
90 μg/L	$9.51	$0.40 - $3.26	$10.10	$0.07 - $0.55
56 μg/L[1]	$9.67	$0.44 - $3.57	$10.28	$0.07 - $0.60
18 μg/L	$16.95	$0.80 - $6.56	$17.96	$0.14 - $1.11
Incremental (from 90 μg/L to 56 μg/L)	$0.16	$0.04 - $0.31	$0.18	$0.0 – 0.05
Incremental (from 56 μg/L to 18 μg/L)	$7.28	$0.36 - $2.99	$7.69	$0.07 - $0.51

Source: [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"E0mmmXDK","properties":{"formattedCitation":"(USEPA, 2018b)","plainCitation":"(USEPA, 2018b)","noteIndex":0},"citationItems":[{"id":1217,"uris":["http://zotero.org/groups/945096/items/P9YD2GRH"],"uri":["http://zotero.org/groups/945096/items/P9YD2GRH"],"itemData":{"id":1217,"type":"article","title":"Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation","author":[{"family":"USEPA","given":""}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}]. Detail may not sum to total because of independent rounding.

1. For the proposed MCL of 56 μg/L and the alternative MCL of 90 μg/L, the national estimates are the same as the estimates based on UCMR 1 data because there were no small system sample results to extrapolate to national small system estimates. At an MCL of 18 μg/L, national estimates include extrapolation for one small system entry point to national estimates based on sampling weights described above.

XIII. Uncertainty Analysis

The EPA provides discussions regarding several sources of uncertainty in the benefit and cost estimates in the Health Risk Reduction and Cost Analysis (USEPA, 2018b). Table XIII-1 provides a summary of sources of uncertainty and their potential effects on estimated costs and benefits. The following discussion addresses uncertainties specific to the benefits analysis.

Table XIII-1. Sources of Uncertainty in Economic Analysis

Description	Potential effect
Baseline Occurrence	
UCMR1 data are more than one decade old; actual occurrence could be lower (e.g., because of contaminant cleanup) or higher (e.g., because new systems use perchlorate-contaminated source water.	± (benefits and costs will change in the same direction)
UCMR1 data include a representative sample of small systems; the data indicates no small systems would exceed 56 µg/L or ~~18~~90 µg/L although it's possible that there are small systems that have baseline perchlorate greater than either MCL.	− (benefits and costs will change in the same direction)
The EPA assumed a uniform distribution of system population served across the entry points for systems with multiple entry points; actual entry point service population could be greater than or less than the estimates.	± (benefits and costs will change in the same direction)
The EPA estimated entry point mean concentrations using the MRL of 4 µg/L as a substitution value for non-detection sample results; actual entry point mean concentrations could be lower.	+ (benefits and costs will change in the same direction)
Benefits Analysis	
The health risks and risk reductions are based on maximum observed measurements that may overstate the risk of exposure to lower concentrations.	+ (benefits only)
The EPA assumed that baseline fT4 is equal to the median, which likely underestimates disease benefits as the logarithmic relationship between maternal fT4 and child IQ leads to larger relative changes in fT4 with increasing levels of perchlorate with lower levels of baseline fT4.	− (benefits only)
The EPA assumed a median TSH feedback loop strength for the exposed population does not incorporate the variability in the feedback mechanism of the body's creation of TSH in response to decreasing fT4.	± (benefits only)
The benefits analysis is based on a single health endpoint (see below for discussion of additional potential endpoints).	− (benefits only)

Description	Potential effect
Cost Analysis	
The EPA assumed that systems requiring treatment would incorporate a safety factor – treating to 80% of the proposed MCL or alternative MCL, which increases costs and benefits.	+ (benefits and costs will change in the same direction)
The EPA assumed that all systems requiring treatment would implement ion exchange, which may overestimate or underestimate costs.	± (costs only)
The EPA developed a monitoring schedule that assumed a uniform distribution of initial monitoring costs over three years; actual costs will vary.	± (costs only)
The EPA assumed that long-term monitoring costs would occur in the last year of the applicable 3-year monitoring period or 9-year monitoring cycle; systems may conduct monitoring in an earlier year of the period or cycle.	− (costs only)
The EPA assumed that 90 percent of ground water systems and 40 percent of surface water systems obtain perchlorate monitoring waivers; the actual percentages may vary.	± (costs only)

1. A "−" symbol indicates that benefits and/or costs will tend to be underestimated. A "+" symbol indicates that benefits and/or costs will tend to be overestimated. A "±" symbol indicates an unknown direction of uncertainty, i.e., benefits and/or costs could be underestimated or overestimated.

The EPA acknowledges the uncertainty regarding the quantitative health risk reduction analysis. In particular, the Agency assumed it could estimate risk reductions based on evidence of a quantifiable relationship between thyroid hormone changes and neurodevelopmental outcomes. The existence of a quantifiable relationship between thyroid hormone changes and neurodevelopmental outcomes has strong support from the literature on the subject; however, not every study identified an association between maternal fT4 and the specified outcome of interest, and the state of the science on this relationship is constantly evolving. The results of the EPA's dose-response literature review identified 31 studies that evaluated the association between maternal thyroid hormone levels and offspring neurodevelopment, with neurodevelopment defined using a variety of endpoints related to cognition, behavior and other outcomes such as schizophrenia. Of these studies, 16 were deemed to potentially possess information that could inform a dose-response relationship. The other 15 only presented data on categorical analyses assessing the impact of maternal hypothyroxinemia on the neurodevelopmental outcomes of interest. Therefore, because the data presented was only a comparison of two groups, there was not information that could be used to inform a dose-response function[16].

Of the 16 studies that potentially had data to inform a dose-response function, 10 evaluated cognition using a variety of tests including various IQ tests (three papers; Ghassabian et al., 2014; Korevaar et al., 2016; Moleti et al., 2016), Bayley Scales of Infant Development (two papers; Pop et al., 1999; Pop et al., 2003), and other validated tests associated with child cognition such as expressive language delay or test performance (five papers; Finken et al., 2013; Henrichs et al., 2010; Kastakina et al., 2006; Noten et al., 2015; Oken et al., 2009). Six of these papers found a statistically significant relationship between maternal fT4, as a continuous variable, and offspring cognitive outcome (Korevaar et al., 2016; Pop et al., 1999; Pop et al., 2003; Finken et al., 2013; Henrichs et al., 2010, Kastakina et al., 2006). However, there were studies where maternal fT4 as a continuous variable was not significantly associated with the outcome of interest. For example, in Ghassabian et al. (2014) the authors found maternal hypothyroxinemia to be associated with an average of a 4.3-point reduction in IQ in their

[16] A complete discussion on the selection of studies to carry through dose-response analysis is presented in section 5.3.4 of the MCLG Approaches report.

offspring compared to offspring of non-hypothyroxinemic mothers. Nevertheless, when assessing the relationship between the continuous measure of maternal fT4 as a continuous variable (across the entire range of fT4 levels) and child IQ, the authors did not find a significant relationship. Additionally, Moleti et al. (2016) found the relationship between maternal fT4 and child IQ to be consistently inversely associated with IQ scores, but their assessment failed to reach statistical significance. This study included fewer than 60 study participants and was considered by the authors to be a pilot assessment.

To consider the evidence on maternal thyroid hormone status on offspring neurodevelopment as a whole, the EPA also reviewed three meta-analyses that assessed the impact of maternal hypothyroxinemia on neurodevelopmental outcomes (including one full systematic review, Thompson et al., 2018). The reviews all concluded maternal hypothyroxinemia is associated with increased risk of cognitive delay, intellectual impairment, or lower scores on performance tests [ADDIN EN.CITE ADDIN EN.CITE.DATA] when considering the entire body of evidence on this topic, not limited to the studies containing data that could potentially be used to describe the relationship between incremental changes in maternal fT4 and incremental changes in child neurodevelopmental outcomes. These conclusions are also supported by the American Thyroid Association, which concluded that the available data "appear to show an association" (p. 337, Alexander et al. 2017) between maternal hypothyroxinemia and neurodevelopment.

In addition to the cognitive effects assessed and modeled, the EPA identified four papers that assessed maternal fT4 status and behavioral outcomes (Endendijk et al., 2017; Ghassabian et al., 2011; Modesto et al., 2015; Oostenbroek et al., 2017), one paper that assessed maternal fT4 status and autism (Roman et al., 2013) and one paper that evaluated odds of a schizophrenia diagnosis as associated with maternal thyroid hormone status (Gyllenberg et al., 2016). From this group of papers, the majority of papers found an association either between maternal hypothyroxinemia or maternal fT4 as a continuous variable and the outcome of interest (Endendijk et al., 2017; Modesto et al., 2015; Oostenbroek etl., 2017; Roman et al., 2013; Gyllenberg et al., 2016). However, this was not always the case as exemplified by Ghassabian et al. (2011) and Gyllenberg et al. (2016). Although Endendijk et al. (2017) found maternal fT4 to have a significant adverse impact on anxiety/depression using the Child Behavioral Check List (CBCL), Ghassabian et al. (2011) did not find any association between maternal thyroid hormone status and offspring score on various components of the CBCL. Additionally, Gyllenberg et al. (2016) found maternal hypothyroxinemia during early to mid-gestation was associated with 70% increased odds of schizophrenia diagnosis in offspring of hypothyroxinemic mothers compared to the offspring of non-hypothyroxinemic mothers. Gyllenberg et al. (2016) also found an association with odds of schizophrenia diagnosis using conditional logistic regression when assessing fT4 as a continuous variable across the entire fT4 range (i.e., not just the hypothyroxinemic range); however, this relationship was attenuated after controlling for smoking. A recently published paper evaluating the EPA's BBDR model and MCLG

Approaches, reiterated the uncertainties the Agency identified in its analyses and questions the use of these quantitative tools for perchlorate in a regulatory context (Clewell et al, 2019).

In summary, not every paper the EPA located in its literature review found a statistically significant association between maternal fT4 as a continuous variable (i.e., the initially identified 16 studies identified as potentially useful to inform a dose-response function) and the neurodevelopmental outcome of interest. However, many studies located in the EPA literature review, several meta-analyses ([HYPERLINK \l "_ENREF_47" \o "Fan, 2016 #307"]; Thompson et al., 2018 and [HYPERLINK \l "_ENREF_187" \o "Wang, 2016 #327"]), the American Thyroid Association (Alexander et al., 2017) and the U.S. EPA's SAB (2013) have concluded there is a relationship between maternal hypothyroxinemia and various neurodevelopmental outcomes. The relationship between maternal fT4 levels and neurodevelopmental outcomes appears strongest in the hypothyroxinemic range, and when looking at the entire range of fT4 as a continuous variable (as opposed to a categorical cut off), the significant relationship between the two variables may dissipate. For the benefits assessment, EPA has concentrated on the neurodevelopmental impacts of changes in fT4 in the lower range of fT4 from the Korevaar et al., (2016) data in an attempt to minimize this uncertainty.

There are a number of potential benefits of reducing perchlorate in drinking water that were not quantified as part of this analysis, which may result in an underestimate of actual benefits. As described by the SAB "children exposed gestationally to maternal hypothyroxinemia (without hypothyroidism) show reduced levels of global and specific cognitive abilities, as well as increased rates of behavior problems including greater dysregulation in early infancy and attentional disorders in childhood (Man et al. 1991; Pop et al. 1999; Pop et al. 2003; Kooistra et al. 2006)" (p. 10, SAB, 2013). EPA's literature review identified relationships between maternal thyroid hormone alterations schizophrenia, ADHD, expressive language delay, reduced school performance and increased odds of autism, among others, none of which are being currently quantified in this assessment. Other potentially omitted benefits include effects of thyroid disorders on cardiovascular disease risk; changes in thyroid hormone levels and their relationship with total cholesterol, LDL cholesterol, and triglycerides; as well as a possible relationship between increases in TSH and risk of fatal coronary heart disease. Treating for perchlorate in drinking water could also potentially remove nitrate, which is a co-occurring contaminant and a goitrogen. These additional potential health endpoints that are not monetized in this benefits analysis (in conjunction with the previously mentioned unaccounted for variability of analysis inputs and uncertainty surrounding the relationship between maternal fT4 and child IQ discussed above) lead to uncertainty regarding the precision of the benefits estimates in this analysis. However, it is unclear whether the analysis as a whole over- or under-estimates the benefits of a reduction of perchlorate in drinking water as the combined uncertainties could have a total effect on the estimated benefits in either direction.

XIV. Request for Comment on Proposed Rule

While all comments relevant to the national primary drinking water regulation for perchlorate proposed today will be considered by the EPA, comments on the following issues will be especially helpful to the EPA in developing a final rule. EPA specifically requests comment on~~:~~ the following topics.

- The adequacy and uncertainties of the underlying ~~technical analysis (~~Health Effects analysis and Methodology for Deriving the Perchlorate ~~Relative Source Contribution (RSC),~~ MCLG including the models, model parameters, points of departure, uncertainty factor, and relative source contribution (Section III~~; Occurrence,~~). The proposed MCLG and MCL of 56 µg/L as well as the alternative MCLG and MCL values of 18 µg/L and of 90 µg/L.
- The adequacy and uncertainties of the underlying analysis of occurrence (Section VI~~;~~), Treatment Technologies~~,~~ (Section X), and the Health Risk Reduction Cost Analysis~~,~~ (Section XII) described in this notice.
- ~~The proposed MCLG and MCL of 56 ug/L as well as the proposed alternative MCLG and MCL of 18 ug/L.~~
- Potential implementation challenges associated with the proposed perchlorate regulation that the EPA should consider, specifically for small systems.
- The Administrator's proposed finding under the SDWA that the calculated benefits associated with the proposed regulation for perchlorate, do not justify the costs as described in Section XII.D of this notice. Specifically, the Administrator finds that: *"The infrequent occurrence of perchlorate at levels of health concern achieves health risk reductions at relatively very few systems, but it imposes high monitoring and administrative cost burdens on public water systems and the States. Based on a comparison of costs and benefits*

estimated at the proposed MCL of 56 µg/L using the best available science and data, the EPA Administrator has determined that the benefits of establishing an NPDWR for perchlorate do not justify the associated costs. In addition, the Administrator also finds that the benefits of an NPDWR at the alternative ~~MCL~~MCLs of 18 ~~ug~~µg/L and 90 µg/L do not justify the resulting rule costs."

SDWA 1412(b) allows the administrator, after notice and opportunity for public comments, to promulgate an MCL that "*maximizes health risk reduction benefits at a cost that is justified by the benefits*." Under this provision, the Agency may consider an alternative MCL that would be set at a level where benefits do justify the costs. However, the alternative MCLs evaluated by EPA would not increase benefits, while compliance costs associated mainly with nationwide CWS monitoring requirements would remain relatively similar.

XV. Request for Comment on Potential Regulatory Determination Withdrawal

The EPA is soliciting comments on withdrawing the 2011 Regulatory Determination (see Section II-C, Regulatory History) based on 1) the findings, described in the occurrence section (section VI) and in the updated health effects assessment (Section III), which suggest that perchlorate does not occur in public water systems with a frequency and at levels of public health concern[17] and that suggest that the Administrator should find that the regulation of perchlorate

[17] As shown in Section VI of this notice there is infrequent occurrence of perchlorate at either 56 µg/L, 18 µg/L or ~~18~~90 µg/L, which are the possible levels expected to cause adverse human health effects.

does not present a meaningful opportunity for health risk reduction for persons served by public water systems. Specifically, perchlorate occurrence information suggests that at an MCL of 56 ~~ug~~μg/L only 2 systems, (0.004% of all water systems in the U.S.) would exceed the regulatory threshold. Only one of these two systems would exceed the alternative MCL of 90 μg/L. In addition, even at an MCL of 18 μg/L, there would only be 15 systems (0.03% of all water systems in the U.S.) that would exceed the regulatory threshold. If, after consideration of public comment, the EPA withdraws the perchlorate determination, there will be no NPDWR for perchlorate, although the EPA can re-list perchlorate on the CCL and proceed to regulation in the future if the occurrence or risk information changes. In the interim, as with other unregulated contaminants, the EPA could address the limited instances of elevated levels of perchlorate by working with the states or using it's SDWA Section 1431 imminent and substantial endangerment or Section 1412(b)(1)(f) health assessment authority, as appropriate.

XVI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action since it raises novel legal or policy issues. It was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

The EPA evaluated the potential costs to States and utilities and the potential benefits of the proposed rule. This analysis, *Health Risk Reduction Cost Analysis of the Proposed Perchlorate Rule (USEPA, 2018b)* is available in the docket and is summarized in section XI.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Cost

This action is expected to be an Executive Order 13771 regulatory action. Details on the estimated costs of this proposed rule can be found in EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*. The information collection requirements are not enforceable until OMB approves them.

The information collected as a result of this rule will allow the States and the EPA to evaluate compliance with the rule. For the first 3-year period following rule promulgation, the major information requirements concern primacy agency activities to implement the rule. Compliance actions for drinking water systems (including monitoring, administration, and treatment costs) do not begin until after Year 3.

The estimate of annual average burden hours for the proposed rule during the first three years following promulgation is 48,539 hours. The annual average cost estimate is $7.4 million for labor. The burden hours per response is 2,648 hours and the cost per response is $134,159. The frequency of response (average responses per respondent) is 1 for primacy agencies, annually (for upfront administrative activities to implement the rule). The estimated number of likely respondents is 55 over the three-year period (for an average of 18.3 each year).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, the EPA has established a public docket for this rule, which includes the ICR, under Docket ID No. **EPA-HQ-OW-2018-0780**. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to

OIRA_submission@omb.eop.gov, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than **[insert date 30 days after publication in the *Federal Register*]**. The EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The Agency has determined that the proposed MCL of 56 μg/L will not result in annual costs that exceed one percent of revenue for small systems affected by the proposed rule.

The small entities subject to the requirements of this action are public water systems serving 10,000 or fewer persons. This is the threshold specified by Congress in the 1996 Amendments to the Safe Drinking Water Act for small system flexibility provisions. In accordance with the RFA requirements, the EPA proposed using this alternative definition in the Federal Register, (63 FR 7620, February 13, 1998), requested public comment, consulted with the Small Business Administration (SBA), and expressed its intention to use the alternative definition for all future drinking water regulations in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). As stated in that final rule, the alternative definition is applied to this proposed regulation.

The proposed rule contains provisions that would affect 58,325 CWS and NTNCWS serving 10,000 or fewer people. In order to meet the proposed rule requirements, all of these systems will need to conduct perchlorate monitoring. At the proposed MCL of 56 μg/L, the UCMR 1 monitoring data indicate that no small systems would be required to incur costs to reduce the levels of perchlorate in drinking water, therefore, all small PWSs will incur monitoring costs only. Impacts on small entities are described in more detail in Chapter 6 of the Health Risk Reduction Cost Analysis of the Proposed Perchlorate Rule (USEPA, 2018b). Table XII-1 shows the annual compliance costs of the proposed rule on the small entities by ownership type. The EPA has determined that no small systems will experience an impact of one percent or greater of average annual revenues (USEPA 2018b).

Table XII-1: Annual Monitoring and Administrative Costs as a Percentage of Average Annual Revenue for Small PWSs

Owner Type	Small Systems	Average Annual Revenues[1]	Average Annualized Costs (as a percent of revenue)	
			3% Discount	7% Discount
Local government	22,716	$1,409,252	$88 (0.006%)	$94 (0.007%)
Private	31,510	$518,439	$88 (0.017%)	$94 (0.018%)
State government	762	$1,409,252	$88 (0.006%)	$94 (0.007%)
Federal government	600	$1,409,252	$88 (0.006%)	$94 (0.007%)
Native American	751	$1,409,252	$88 (0.006%)	$94 (0.007%)
Public/Private	1,825	$518,439	$88 (0.017%)	$94 (0.018%)
Unclassified	161	$518,439	$88 (0.017%)	$94 (0.018%)
Total	58,325	$838,719	$88 (0.010%)	$94 (0.010%)

1. Based on Community Water System Survey [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"ZkgC4dzL","properties":{"formattedCitation":"(USEPA, 2009c Table 65)","plainCitation":"(USEPA, 2009c Table 65)","noteIndex":0},"citationItems":[{"id":924,"uris":["http://zotero.org/groups/945096/items/DZNAAV6M"],"uri":["http://zotero.org/groups/945096/items/DZNAAV6M"],"itemData":{"id":924,"type":"article","title":"2006 Community Water System Survey - Volume II: Detailed Tables and Survey Methodology","URL":"https://www.epa.gov/dwstandardsregulations/community-water-system-survey","author":[{"literal":"USEPA"}],"issued":{"date-parts":[["2009",5]]},"accessed":{"date-parts":[["2018",8,17]]}},"suffix":"Table 65"}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}] and updated to 2017$ based on the chained consumer price index for fuels and utilities in U.S. city average, all urban consumers [ADDIN ZOTERO_ITEM CSL_CITATION {"citationID":"rkwEpGYT","properties":{"formattedCitation":"(Bureau of Labor Statistics (BLS), 2018a)","plainCitation":"(Bureau of Labor Statistics (BLS), 2018a)","noteIndex":0},"citationItems":[{"id":984,"uris":["http://zotero.org/groups/945096/items/E3I7HRK8"],"uri":["http://zotero.org/groups/945096/items/E3I7HRK8"],"itemData":{"id":984,"type":"article","title":"Chained consumer price index for fuels and utilities in U.S. city average, all urban consumers, 2000 to 2018","author":[{"literal":"Bureau of Labor Statistics (BLS)"}],"issued":{"date-parts":[["2018"]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}].

E. Unfunded Mandates Reform Act

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538. The action imposes minimal enforceable duty on any state, local or tribal governments or the private sector

Based on the cost estimates detailed in Section XI, the EPA determined that compliance costs in any given year would be below the threshold set in UMRA, with maximum single-year costs of approximately $10.2 million. The EPA has determined that this rule contains a federal mandate that would not result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects of greater than $25 million on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Annual costs are estimated to range from $9.6 million at a 3 percent discount rate to $10.2 million using a 7 percent, with $6.5 million to $7.0 million annually accruing to public entities. The EPA has concluded that this proposed rule may be of interest because it may impose direct compliance costs on State or local governments, and the federal government will not provide the funds necessary to pay those costs.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

The EPA has concluded that this proposed rule may have Tribal implications, because it may impose direct compliance costs on Tribal governments, and the federal government would not provide the funds necessary to pay those costs. The EPA has identified 768 water systems with 1,167 entry points under Native American ownership that may be subject to the proposed rule. They would bear an estimated total annualized cost of $74,100 at a 3 percent discount rate ($79,625 at 7 percent) to implement this rule as proposed, with all costs attributable to monitoring and administrative costs. Estimated average annualized cost per system ranges from $96 at a 3 percent discount rate to $104 at a 7 percent discount rate.

Accordingly, the EPA provides the following Tribal summary impact statement as required by section 5(b) of Executive Order 13175. The EPA consulted with representatives of

Tribal officials early in the process of developing this proposed regulation to permit them to have meaningful and timely input into its development. The EPA conducted consultation with Indian Tribes which included a public meeting in February 28, 2012 to request input and provide rulemaking information to interested parties. A meeting summary report is available on the docket for public inspection (USEPA 2012). The EPA notes that 751 of the 768 Tribal systems identified by the Agency as subject to the proposed rule are small systems that are expected to incur only monitoring costs. Due to the health risks associated with perchlorate, capital expenditures needed for compliance with the rule would be eligible for federal funding sources, specifically the Drinking Water State Revolving Fund. In the spirit of Executive Order 13175, and consistent with the EPA policy to promote communications between the EPA and Tribal governments, the EPA specifically solicits additional comment on this proposed rule from Tribal officials.

H. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866; however, the environmental health risk addressed by this action may have a disproportionate effect on children. Accordingly, the EPA evaluated the environmental health or safety effects of perchlorate on children. The results of this evaluation are contained in the Health Effects Technical Support Document (USEPA 2018a) and described in section III of this preamble. The EPA has evaluated the risk associated with perchlorate in drinking water for the sensitive subpopulation – offspring of pregnant women exposed to perchlorate during the first trimester – and established a proposed MCLG that is protective of this subpopulation as well as other children. The EPA also estimated the health risk reduction of the proposed and alternative MCLs. This analysis is described in the Health Risk Reduction and Cost Analysis for the proposed rule (USEPA 2018b) and is summarized in section XI of this preamble. Copies of the Health Effects Technical Support Document and Economic Analysis and supporting information are available in the public docket for today's proposal.

I. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This determination is based on the following analysis.

The first consideration is whether the proposed rule would adversely affect the supply of energy. The proposed rule does not regulate power generation, either directly or indirectly. The public and private water systems that the proposed rule regulates do not generate power. Further, the cost increases borne by customers of water utilities as a result of the proposed rule are a low percentage of the total cost of water, except for a few water systems that might install treatment technologies and would likely spread that cost over their customer base. In sum, the proposed rule does not regulate the supply of energy, does not generally regulate the utilities that supply energy, and is unlikely to affect significantly the customer base of energy suppliers. Thus, the proposed rule would not translate into adverse effects on the supply of energy.

The second consideration is whether the proposed rule would adversely affect the distribution of energy. The proposed rule does not regulate any aspect of energy distribution. The water systems that are regulated by the proposed rule already have electrical service. At the proposed MCL, one entry point at one system may require incremental power to operate new treatment processes. The increase in peak electricity demand at water utilities is negligible. Therefore, the EPA estimates that the existing connections are adequate and that the proposed rule has no discernable adverse effect on energy distribution.

The third consideration is whether the proposed rule would adversely affect the use of energy. Because only one system is expected to add treatment technologies that use electrical power, this potential impact on sector demand or overall national demand for power is negligible.

Based on its analysis of these considerations, the EPA has concluded that proposed rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

J. National Technology Transfer and Advancement Act of 1995

The proposed rule could involve voluntary consensus standards in that it would require monitoring for Perchlorate. The EPA proposed five analytical methods for the identification and quantification of perchlorate in drinking water. EPA methods 314.0, 314.1, 314.2, 331.0, and

332.0 incorporate quality control criteria which allow accurate quantitation of perchlorate. Additional information about the analytical methods is available in section VII of this notice.

The EPA's monitoring and sampling protocols generally include voluntary consensus standards developed by agencies such as ASTM International, Standard Methods and other such bodies wherever the EPA deems these methodologies appropriate for compliance monitoring. The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA has determined that this proposed rule would not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it would increase the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

The public is invited to comment on this aspect of the proposed rulemaking and, specifically, to recommend additional methods to address Environmental Justice concerns from establishing a drinking water rule for perchlorate in drinking water.

XVII. Consultations with the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with sections 1412(d) and 1412(e) of the Safe Drinking Water Act (SDWA), the Agency consulted with the National Drinking Water Advisory Council (NDWAC or the Council); the Secretary of Health and Human Services; and with the EPA Science Advisory Board. The Agency consulted with NDWAC during the Council's October 4-5, 2012 meeting. A summary of the NDWAC recommendations is available in the National Drinking Water Advisory Council, Fall 2012 Meeting Summary Report (NDWAC 2012b) and the docket for this proposed rule. The EPA carefully considered NDWAC recommendations during the development of a proposed drinking water rule for perchlorate.

On May 29, 2012, the EPA sought guidance from the EPA Science Advisory Board (SAB) on how best to consider and interpret life stage information, epidemiological and biomonitoring data since the publication of the National Research Council 2005 report, the Agency's physiologically-based pharmacokinetic (PBPK) analyses, and the totality of perchlorate health information to derive a Maximum Contaminant Level Goal (MCLG) for perchlorate (U.S. EPA 2012, NRC 2005). On May 29, 2013, the EPA received significant input from SAB, summarized in the report, SAB Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate (U.S. EPA 2013a).

On July 15, 2013, the EPA responded by stating that the Agency would consider all the recommendations from the SAB, as it continued working on the development of the rulemaking process for perchlorate (U.S. EPA 2013b). To address SAB recommendations, the EPA collaborated with Food and Drug Administration (FDA) scientists to develop PBPK/pharmacodynamic (PD), or biologically based dose-response (BBDR), models that incorporate all available health related information on perchlorate to predict changes in thyroid hormones in sensitive life stages exposed to different dietary iodide and perchlorate levels (U.S. EPA 2017). As recommended by SAB, the EPA developed these models based upon perchlorate's mode of action (i.e., iodide uptake inhibition by the thyroid) (U.S. EPA 2013a). Additional details are in section III.C. of this notice and in the Health Effects of Perchlorate support document located in the docket for this proposed rule.

In accordance with SAB recommendations, the EPA developed a two-stage approach to integrate BBDR model results with data on neurodevelopmental outcomes from epidemiological studies, this approach allowed the Agency to link maternal thyroid hormones levels as a result of low iodine intake and perchlorate exposure, to derive an MCLG that directly addresses the most sensitive life stage (U.S. EPA 2013a).

On ~~[INSERT DATE]~~ March 25, 2019, the EPA consulted with the Department of Health and Human Services (HHS). EPA provided information to HHS officials on the draft proposed perchlorate regulation and considered HHS input **[OPEN ITEM, WE WILL UPDATE THIS SECTION TO REFLECT HHS ~~CONSULTATION~~INPUT THAT WILL ~~TAKE PLACE~~BE RECEIVED DURING INTER AGENCY REVIEW]**

XVIII. References

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List of Subjects in 40 CFR Parts 141, and 142

Administrative practice and procedure, Chemicals, Indians-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated:____________________

____

Andrew R. Wheeler,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency proposes to amend 40 CFR part 141 and 40 CFR part 142 as follows:

PART 141 - NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for part 141 continues to read as follows:

   Authority: 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9, and 300j-11.

2. Amend § 141.6 by revising paragraph (a) and adding paragraph (l).
3. Amend § 141.23 by:
   a. Revising the title in the table in paragraph (a)(4)(i);
   b. Adding "Perchlorate" in alphabetical order, in the table in paragraph (a)(4)(i);
   c. Adding "perchlorate" in paragraph (a)(5);
   d. Adding "perchlorate" in alphabetical order, in paragraph (c);
   e. Adding paragraph (c)(10);
   f. Adding "perchlorate" in alphabetical order, in paragraph (f)(1);
   g. Adding "perchlorate" in alphabetical order, to the first sentence in paragraph (i)(1);
   h. Adding "perchlorate" in alphabetical order, to the first sentence in paragraph (i)(2);
   i. Revising paragraph (i)(3);
   j. Revising paragraph (k)(1);

k. Adding "perchlorate" in alphabetical order, to the second sentence in paragraph (k)(1);

l. Adding an entry for "21. Perchlorate" in alphabetical order, in the table in paragraph (k)(1);

m. Adding "perchlorate" in alphabetical order, to paragraph (k)(2);

n. Adding "Perchlorate" in alphabetical order, in the table in paragraph (k)(2);

o. Adding "perchlorate" in alphabetical order, to the third sentence in paragraph (k)(3); and

p. Adding an entry for "Perchlorate" in alphabetical order, in the table in paragraph (k)(3)(ii).

4. Amend § 141.51 by adding an entry for "Perchlorate" in alphabetical order, in the table in paragraph (b).

5. Amend § 141.60 by adding paragraph (b)(5).

6. Amend § 141.62 by:

   a. Adding an entry (17) for "Perchlorate" in paragraph (b);

   b. Adding an entry for "Perchlorate" in alphabetical order, to the table in paragraph (c);

   c. Adding an entry "14 = Biological Treatment" in the table Key to BATs in paragraph (c);

   d. Adding paragraph (e); and

   e. Adding a table in paragraph (e).

7. Amend Appendix A to Subpart O of Part 141 by adding an entry for "Perchlorate" in the table entitled "APPENDIX A TO SUBPART O OF PART 141 – REGULATED CONTAMINANTS."

8. Amend Appendix A to Subpart Q of Part 141 by adding an entry for "Perchlorate" in the table entitled "APPENDIX A TO SUBPART Q OF PART 141 - NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTIFICATION."
9. Amend Appendix B to Subpart Q of Part 141 by adding an entry for "Perchlorate" in the table entitled "APPENDIX B TO SUBPART Q OF PART 141 – STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION."

The revisions and additions read as follows:

Subpart A—General

*****

§ 141.6 Effective Dates.

(a) Except as provided in paragraphs (b) through (l) of this section the regulations set forth in this part shall take effect on June 24, 1977.

*****

(l) The regulations contained in the revisions to §§141.23(a)(4)(i), 141.23(a)(5), 141.23(c),141.23(f)(1), 141.23(i)(1)-(2), 141.23(k)(1)-(3), 141.23(k)(3)(ii), 141.51(b), 141.60(b)(5), 141.62(b), 141.62(c), 141.62(e), Appendix A to Subpart O and Appendix A and B to Subpart Q are effective for the purposes of compliance on [insert date].

Subpart C—Monitoring and Analytical Requirements

*****

§141.23 Inorganic chemical sampling and analytical requirements.

*****

(a)***

(4)***

(i)***

DETECTION LIMITS FOR INORGANIC CONTAMINANTS (COMPOSITED SAMPLES)

Contaminant	MCL (mg/l)	Methodology	Detection limit (mg/l)
*******	*******	*******	*******

Perchlorate	0.056	Ion Chromatography Inline Column Concentration/Matrix Elimination Ion Chromatography with Suppressed Conductivity Detection Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection Liquid Chromatography Electrospray Ionization Mass Spectrometry Ion Chromatography with Suppressed Conductivity and Electrospray Ionization Mass Spectrometry	0.00053 0.00003 0.000012-0.000018 0.000005 (Tandem Mass Spectrometry [MS/MS]) 0.000008 (Selected Ion Monitoring [SIM]) 0.00002
*******	*******	*******	*******

*****

*****

(c)***

(10) Community water systems and non-transient non-community water systems must conduct initial monitoring for perchlorate as follows:

(i) Community water systems serving greater than 10,000 persons without acceptable historic data, as defined below, must collect four consecutive quarterly samples at all sampling points between January 1, 2023 and December 31, 2025.

(ii) Community water systems serving 10,000 or fewer persons and non-transient non-community water systems without acceptable historic data, as defined below, must collect four consecutive quarterly samples at all sampling points between January 1, 2026 and December 31, 2028.

(iii) Grandfathering of data: States may allow historical monitoring data collected at a sampling point to satisfy the initial monitoring requirements for that sampling point, for the following situations.

(A) To satisfy initial monitoring requirements, community water systems serving greater than 10,000 persons having only one entry point to the distribution system may use the monitoring data from the compliance monitoring period between January 1, 2020 and December 31, 2022. Community water systems serving 10,000 or fewer persons and non-transient non-community water systems having only one entry point to the distribution system may use the monitoring data from the compliance monitoring period between January 1, 2023 and December 31, 2025.

(B) To satisfy initial monitoring requirements, a system with multiple entry points and having appropriate historical monitoring data for each entry point to the distribution system may use the monitoring data from the compliance monitoring period that began between January 1, 2020 and December 31, 2022 for community water systems serving greater than 10,000 persons and between January 1, 2023 and December 31, 2025 for community water systems serving 10,000 or fewer persons and for non-transient non-community water systems.

(C) To satisfy initial monitoring requirements, a system with appropriate historical data for a representative point in the distribution system may use the monitoring data from the compliance monitoring period between January 1, 2020 and December 31, 2022 for community water systems serving greater than 10,000 persons and between January 1, 2023 and December 31, 2025 for community water systems serving 10,000 or fewer persons and for non-transient non-community water systems, provided that the State finds that the historical data satisfactorily demonstrate that each entry point to the distribution system is expected to be in compliance based upon the historical data and reasonable assumptions about the variability of contaminant levels between entry points. The State must make a written finding indicating how the data conforms to these requirements.

(iv) The State may waive the final two quarters of initial monitoring for perchlorate for a sampling point if the results of the samples from the previous two quarters are below the detection limit.

*****

(i)***

(3) Compliance with the maximum contaminant level for nitrate, nitrite and perchlorate is determined based on one sample if the levels of these contaminants are below the MCLs. If the level of perchlorate exceeds the MCL in the initial sample, a confirmation sample is required in accordance with paragraph 141.23(f)(1) and compliance shall be

based on the average of the initial and confirmation sample. If the levels of nitrate and/or nitrite exceed the MCLs in the initial sample, a confirmation sample is required in accordance with paragraph 141.23(f)(2) and compliance shall be based on the average of the initial and confirmation sample.

*****

(k)***

(1) Analysis for the following contaminants shall be conducted in accordance with the methods in the following table, or the alternative methods listed in Appendix A to subpart C of this part, or their equivalent as determined by the EPA.

*****

Contaminant	Methodology[13]	EPA	ASTM[3]	SM[4] (18th, 19th ed.)	SM[4] (20th ed.)	SM Online[22]	Other
******	******	*******	*******	*******	*******	*******	*******
Perchlorate	Ion Chromatography	314.0					
	Inline Column Concentration/Matrix Elimination Ion Chromatography with Suppressed Conductivity Detection	314.1					
	Two-Dimensional Ion Chromatography with Suppressed	314.2					

	Conductivity Detection Liquid Chromatography Electrospray Ionization Mass Spectrometry Ion Chromatography with Suppressed Conductivity and Electrospray Ionization Mass Spectrometry	 331.0 332.0					
******	*******	*******	*******	*******	*******	*******	*******

*****

[3]Annual Book of ASTM Standards, ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428, http://www.astm.org.; Annual Book of ASTM Standards 1994, Vols. 11.01 and 11.02; Annual Book of ASTM Standards 1996, Vols. 11.01 and 11.02; Annual Book of ASTM Standards 1999, Vols. 11.01 and 11.02; Annual Book of ASTM Standards 2003, Vols. 11.01 and 11.02.

*****

[4]Standard Methods for the Examination of Water and Wastewater, American Public Health Association, 800 I Street NW., Washington, DC 20001-3710; Standard Methods for the Examination of Water and Wastewater, 18th edition (1992); Standard Methods for the Examination of Water and Wastewater, 19th edition (1995); Standard Methods for the

Examination of Water and Wastewater, 20th edition (1998).The following methods from this edition cannot be used: 3111 B, 3111 D, 3113 B, and 3114 B.

*****

[13]Because MDLs reported in EPA Methods 200.7 and 200.9 were determined using a 2x preconcentration step during sample digestion, MDLs determined when samples are analyzed by direct analysis (i.e., no sample digestion) will be higher. For direct analysis of cadmium and arsenic by Method 200.7, and arsenic by Method 3120 B, sample preconcentration using pneumatic nebulization may be required to achieve lower detection limits. Preconcentration may also be required for direct analysis of antimony, lead, and thallium by Method 200.9; antimony and lead by Method 3113 B; and lead by Method D3559-90D, unless multiple in-furnace depositions are made.

*****

[22]Standard Methods Online, American Public Health Association, 800 I Street NW., Washington, DC 20001, available at http://www.standardmethods.org. The year in which each method was approved by the Standard Methods Committee is designated by the last two digits in the method number. The methods listed are the only online versions that may be used.

*****

(2)***

Contaminant	**Preservative[1]**	**Container[2]**	**Time[3]**
*******	*******	*******	*******
Perchlorate[7]	4 °C	P or G	28 days
*******	*******	*******	******

[1]For cyanide determinations samples must be adjusted with sodium hydroxide to pH 12 at the time off collection. When chilling is indicated the sample must be shipped and stored at 4 °C or less. Acidification of nitrate or metals samples may be with a concentrated acid or a dilute (50% by volume) solution of the applicable concentrated acid. Acidification of samples for metals analysis is encouraged and allowed at the laboratory rather than at the time of sampling provided the shipping time and other instructions in Section 8.3 of EPA Methods 200.7 or 200.8 or 200.9 are followed.

[2]P = plastic, hard or soft; G = glass, hard or soft.

[3]In all cases samples should be analyzed as soon after collection as possible. Follow additional (if any) information on preservation, containers or holding times that is specified in method.

*****

[7] Sample collection for perchlorate shall be conducted following the requirements specified in the approved methods in 141.23(k)(1) or the alternative methods listed in appendix A of subpart C of this part, or their equivalent as determined by the EPA.

*****

(3)***

(ii)***

Contaminant	Acceptance limit
*******	*******
Perchlorate	$\pm$20% at $\geq$0.004 mg/L

*******	*******

*****

Subpart F—Maximum Contaminant Level Goals and Maximum Residual Disinfectant Level Goals

*****

§141.51 Maximum contaminant level goals for inorganic contaminants.

*****

(b)***

Contaminant	**MCLG (mg/l)**
*******	*******
Perchlorate	0.056
*******	*******

*****

Subpart G—National Primary Drinking Water Regulations: Maximum Contaminant Levels and Maximum Residual Disinfectant Levels

§141.60 Effective dates.

(a) ***

(5) The effective date for §141.62(b)(17) is [insert date].

§141.62 Maximum contaminant levels for inorganic contaminants.

*****

(b)***

Contaminant	MCL (mg/l)
*******	*******
(17) Perchlorate	0.056

(c)***

BAT FOR INORGANIC COMPOUNDS LISTED IN SECTION 141.62(b)

Chemical Name	BAT(s)
*******	********
Perchlorate	5, 7, 14
*******	*******

*****

Key to BATs in Table

*****

5 = Ion Exchnage

*****

7 = Reverse Osmosis

*****

14 = Biological Treatment

*****

(e)The Administrator, pursuant to section 1412 of the Act, hereby identified in the following table the affordable technology, treatment technique, or other means available to systems serving 10,000 persons or fewer for achieving compliance with the maximum contaminant level for perchlorate:

SMALL SYSTEM COMPLIANCE TECHNOLOGIES (SSCTs) FOR PERCHLORATE

Small system compliance technology	**Affordability for listed small system categories**
Ion exchange	All size categories.
Reverse osmosis (point of use)	All size categories

Subpart O – Consumer Confidence Reports

*****

APPENDIX A TO SUBPART O OF 141 – REGUATED CONTAMINANTS

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
********	*******	*******	*******	*******	*******	*******
Inorganic contaminants						
********	********	********	*******	*******	*******	*******

Perchlorate	0.056	1000	56	56	Perchlorate is commonly used in solid rocket propellants, munitions, fireworks, airbag initiators for vehicles, matches and signal flares. Perchlorate may occur naturally, particularly in arid regions such as the southwestern United States and is found as a natural impurity in nitrate salts used to produce nitrate fertilizers, explosives and other products.	Offspring of pregnant women and infants who drink water containing perchlorate in excess of the MCL could experience delays in their physical or mental development.
*******	*******	*******	*******	*******	*******	*******

Subpart Q – Public Notification of Drinking Water Violations

*****

APPENDIX A TO SUBPART Q OF PART 141 – NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE[1]

Contaminant	MCL/MRDL/TT violations[2]	Monitoring & testing procedure violations

	Tier of public notice required	Citation	Tier of public notice required	Citation
*******				
B. Inorganic Chemicals (IOCs)				
*******				
14. Perchlorate	1	141.62(b)	3	141.23(a), (c), 141.23(f)(1)
*******				

[1] Violations and other situations not listed in this table (e.g., failure to prepare Consumer Confidence Reports), do not require notice, unless otherwise determined by the primacy agency. Primacy agencies may, at their option, also require a more stringent public notice tier (e.g., Tier 1 instead of Tier or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under 141.202(a) and 141.203(a).

[2] MCL-Maximum contaminant level, MDRL-Maximum residual disinfectant level, TT-treatment technique

*****

APPENDIX B TO SUBPART Q OF PART 141 – STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
*******			
C. Inorganic Chemicals (IOCs)			
*******	*******	*******	*******
21. Perchlorate	0.056	0.056	Offspring of pregnant women and infants who drink water containing perchlorate in excess of the MCL could experience delays in their physical or mental development.
*******	*******	*******	*******

[1] MCLG – Maximum contaminant level goal

[2] MCL – Maximum contaminant level

PART 142 - NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

1. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9, and 300j-11.

2. In § 142.62:

a. Add an entry for "Perchlorate" to the table in paragraph (b); and

b. Add entry "14 = Biological Treatment" in the table's *Key to BATs* in paragraph (b).

Subpart G – Identification of Best Technology, Treatment Techniques or Other Means Generally Available.

*****

§142.62 Variances and exemptions from the maximum contaminant levels for organic and inorganic chemicals.

*****

(b)***

BAT FOR INORGANIC COMPOUNDS LISTED IN §141.62(b)

Chemical Name	BAT(s)
*******	********
Perchlorate	5, 7, 14
*******	*******

*****

Key to BATs in Table

*****

5 = Ion Exchange

*****

Message

From: Wadlington, Christina [Wadlington.Christina@epa.gov]
Sent: 8/4/2016 12:36:11 PM
To: Grevatt, Peter [Grevatt.Peter@epa.gov]
CC: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Oshida, Phil [Oshida.Phil@epa.gov]; Greene, Ashley [Greene.Ashley@epa.gov]; Harris, Adrienne [Harris.Adrienne@epa.gov]
Subject: Perchlorate Roll Out
Attachments: Perchlorate Roll Out_8.3.16.docx

Peter,

Provided is a draft of the Perchlorate Communications Roll Out for your review.

Please note, some of the questions were left in yellow highlights, in case you want to remove them because we should defer them to FDA or they are not ready to share at this time.

Please let Lisa/I know if you have any questions.
Thank you.

Christina Wadlington
Communications Director
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
Tel: 202.566.1859
Email: wadlington.christina@epa.gov
Webpage: www.epa.gov/safewater

Perchlorate Peer Review
Communications Plan

PRE-PUBLICATION RELEASE DATE: TBD (approximately August 19, 2016)

ACTION: The agency is undertaking an independent, external panel peer review and announces the release of several materials for public comment that relate to the development of a maximum contaminant level goal for perchlorate.

KEY MESSAGES

- Perchlorate can disrupt the normal function of the thyroid gland in both children and adults.
- Perchlorate is of particular concern to infant and fetal nervous system development.
- The agency is releasing peer review materials that relate to the development of the Maximum Contaminant Level Goal (MCLG) for perchlorate.
- Based on the recommendations made by the SAB, EPA and FDA developed a biologically-based dose response (BBDR) model that can be used to derive an MCLG. Previously, EPA used a reference-dose to establish EPA's interim health advisory level of 15 ppb.
- The use of the BBDR model to inform an MCLG is precedent-setting, therefore EPA is conducting a transparent and rigorous expert peer review process.
- After the peer review is complete, EPA will take the next appropriate steps.

ANTICIPATED REACTION

There is likely to be considerable interest and response to EPA's release of peer review materials and the peer review process itself. Over the past several years stakeholders have provided extensive comments on publically reviewable perchlorate materials and notices, met with EPA senior officials, managers and staff and have wrote the Administrator numerous letters.

EPA was recently sued by NRDC for the Agency's failure to issue proposed and final regulatory actions for perchlorate in accordance with the timelines provided in SDWA. EPA is currently negotiating with the petitioner to establish an agreeable schedule for development of the proposed action.

Stakeholders and the press are aware that EPA has been working to implement SAB recommendations and develop a BBDR model and approach to inform development of an MCLG.

Stakeholders will generally be critical of the highly technical, underlying science to model perchlorate in sensitive life stages and the novel application of the model output to inform the derivation of a perchlorate MCLG.

- Industry groups (Perchlorate Study Group, American Chemistry Council); drinking water utilities, the U.S. Chamber of Commerce and the Department of Defense will likely be critical of the underlying science and that the peer review process was expedited
- Environmental groups will likely be critical of the underlying science
- Consumers, both those using public water systems and private wells, will be concerned about potential health risks from perchlorate
- Congressional interest – Senator Boxer

DESK STATEMENT

The agency is releasing peer review materials that relate to the development of the Maximum Contaminant Level Goal (MCLG) for perchlorate. The materials include an interim list of peer review candidates, charge questions, the BBDR model and report, and a report on methodologies for approaches to apply modeling outputs to the development of the MCLG. EPA developed the BBDR model with contributions from Food and Drug Administration scientists. EPA will consider public and peer reviewer comments submitted in accordance with the Federal Register notice when finalizing the peer review products. After the peer review is complete, EPA will take the next appropriate steps.

Background

On January 8, 2009, EPA released an interim drinking water health advisory of 15 parts of perchlorate for every billion parts of water (parts per billion or ppb). This level was determined using a reference dose based on the recommendation of the National Research Council (NRC).

In 2011, EPA announced its decision (76 FR 7762) to regulate perchlorate under the Safe Drinking Water Act (SDWA). In accordance with SDWA, the Agency requested EPA's Science Advisory Board (SAB) to review how to consider available data in deriving a Maximum Contaminant Level Goal (MCLG) for use in developing a perchlorate National Primary Drinking Water Regulation. The MCLG is a non-enforceable goal defined under the SDWA as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The MCLG is one of the considerations in developing the enforceable maximum contaminant level (MCL) for a regulated contaminant. The SAB released its final report on May 29, 2013 and recommended that EPA "derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling."

As recommended by the SAB, the agency, with contributions from FDA scientists, developed a BBDR model to determine under what conditions of iodine nutrition and exposure to perchlorate, that infants and lactating mothers would experience hypothyroxinemia (changes in thyroid hormone levels). EPA also developed approaches for deriving a perchlorate MCLG by using relationships from published literature to connect the changes in thyroid levels, as predicted by the BBDR model, to the development of the neurological system in infants and lactating mothers.

COMMUNICATIONS MATERIALS

External:

- Webpage (link will appear on https://www.epa.gov/dwstandardsregulations/perchlorate) will include:
    - Pre-publication notice
    - Link to Draft BBDR model
    - BBDR model accompanying report
    - Draft report on the application of the model to inform the development of a perchlorate MCLG
    - Peer review charge questions
- External Q&A (Consumer and Peer Review)
- Fact Sheet (Based on External Consumer Q&A)

Internal:

- Communications Plan with Roll out schedule
- Notification List
- Q&A

Perchlorate Peer Review
Communications Plan

RELEASE SCHEDULE

-3 days

- OGWDW notification to Regional Contacts
- OPA notification to Regional PADS

-2 days

- OGWDW notification to federal partners (FDA, ATSDR, NIEHS)
- OPA calls to federal agencies' communications

Pre-Pub release day [tbd]

9:00 a.m	Begin head's up calls to stakeholder list below
10:00 a.m	Congressional heads up emails
12:00 p.m	Website goes live – Broader congressional notifications (emails with link to website).
1:00 p.m	Social media and stakeholder notification via email (Water Headlines listserv)

STAKEHOLDER NOTIFICATION

OGWDW:

- Michael Deane, Director, National Association of Water Companies
- Tracy Mehan, Government Affairs Director, American Water Works Association
- Mike Paque, Executive Director, Groundwater Protection Council
- Jim Taft, Executive Director, Association of State Drinking Water Administrators
- Lynn Thorp, National Campaigns Director, Clean Water Action
- Diane Van de Hei, Executive Director, Association of Metropolitan Water Agencies
- Sam Wade, Executive Director, National Rural Water Association
- Mae Wu, Natural Resources Defense Council

OLEM (OSRTI):

- Association of State and Territorial Solid Waste Management Officials

EXTERNAL QUESTIONS AND ANSWERS

CONSUMER QUESTIONS

Where is perchlorate found?

Perchlorate occurs naturally in arid states in the Southwest United States, in nitrate fertilizer deposits in Chile, and in potash ore in the United States and Canada. It also forms naturally in the atmosphere. Perchlorate can be manufactured and used as an industrial chemical and can be found in rocket propellant, explosives, fireworks and road flares. It has also been found in some public drinking water systems and in food.

Why is perchlorate in drinking water a health concern?

Perchlorate can disrupt the normal function of the thyroid gland in both children and adults. In adults, the thyroid plays an important role in metabolism, making and storing hormones that help regulate the heart rate, blood pressure, body temperature, and the rate at which food is converted into energy. In fetuses and infants, thyroid hormones are critical for normal growth and development of the central nervous system. Perchlorate can interfere with the human body's ability to absorb iodine into the thyroid gland which is a critical element in the production of thyroid hormones.

Perchlorate Peer Review
Communications Plan

How does perchlorate get into my drinking water?
Perchlorate dissolves easily, is relatively stable and is mobile in water. While it has often been detected in water supplies in close proximity to sites where solid rocket fuel is manufactured or used, there are also locations in the United States lacking a clearly defined source.

Besides drinking water, how else can people be exposed to perchlorate?
People are exposed to perchlorate primarily through eating contaminated food or drinking water. The Food and Drug Administration (FDA) Total Diet Study combines nationwide sampling and analysis of hundreds of food items along with national surveys of food intake to develop comprehensive dietary exposure estimates for a variety of demographic groups in the U.S. In the 2005-2006 survey the FDA found detectable levels of perchlorate in 74 percent of the foods sampled. The complete set of FDA perchlorate data can be found here: [HYPERLINK "http://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm077685.htm"]

Have public drinking water systems been sampled for perchlorate?
Customers served by a public water system can contact their local water supplier and ask if they test for perchlorate. If you are concerned about the possibility of perchlorate in your drinking water and you are served by a private well, EPA recommends testing your drinking water. In addition, EPA recommends that residents reach out to their local public health department for more information. More information about private wells can be found here: [HYPERLINK "http://www.epa.gov/privatewells" \h].

I live in a community with elevated perchlorate levels. Who do I call to get more information about what my utility is doing to address the elevated levels?
Contact your local water supplier to find out more about perchlorate in your drinking water. If you don't know who your local water supplier is, the information should be included in your latest water bill.

I get my tap water from a private well. How can I find out if perchlorate is in my water?
If you are concerned about the possibility of perchlorate in your drinking water and you are served by a private well, EPA recommends testing your drinking water. Approved laboratories can analyze a sample of your water to determine whether perchlorate is present and at what concentrations. More information about private wells can be found here: [HYPERLINK "http://www.epa.gov/privatewells" \h].

Can a person drink tap water containing perchlorate at or below the level of the health advisory every day of their life and not expect adverse health effects from these chemicals? [CONFIRM WITH OST]
Yes, the Interim Drinking Water Health Advisory of 15 micrograms per liter (µg/L) is a concentration of a perchlorate in drinking water that is not expected to cause any adverse effects for a lifetime of exposure.

Can perchlorate be boiled out of my water?
No, perchlorate cannot be removed by heating or boiling water.

Should I be worried about making infant formula with tap water? [from FDA language]

Perchlorate Peer Review
Communications Plan

If you live in an area where perchlorate is in drinking water at levels above 15 parts per billion, FDA recommends using water that is lower in perchlorate levels, such as bottled water or water from a home treatment device certified for perchlorate removal, for your infant's formula. FDA: [HYPERLINK "http://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm077572.htm" \l "tapwater"]

Should I consider taking iodine dietary supplements if I am worried about perchlorate? [from FDA language]
If you eat a healthy diet, the FDA believes that taking iodine dietary supplements is not necessary to protect you from the health effects associated with perchlorate at the levels present in water and foods.

Sources of iodine include milk and dairy products, grains, and seafood, as well as dietary supplements such as multi-vitamins. Iodized table salt is also a source of iodine, but salt should be used sparingly, in accordance with the dietary guidelines for sodium intake.

Iodine is necessary for a baby's normal brain development, so it is particularly important for pregnant and nursing women to get adequate amounts of iodine. Many over-the-counter and prescribed prenatal supplements contain iodine.
[HYPERLINK "http://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm077572.htm" \l "elevated"]

How does a utility reduce/remove perchlorate?
A number of options are available to drinking water systems to lower concentrations of perchlorate in the drinking water supply. In some cases, drinking water systems may be able to reduce concentrations of perchlorate by closing contaminated wells or changing rates of blending of water sources.

Perchlorate can be removed using a number of advanced treatment technologies. Each technology has advantages and disadvantages depending on the level of perchlorate present in the source water, removal goals, other water quality parameters, competing treatment objectives, and treatment waste disposal options. Regenerable and single-pass ion exchange, reverse osmosis, and fixed- and fluidized-bed biological treatment can all remove perchlorate from drinking water sources.

These treatment technologies are used by some public water systems today, but should be carefully designed and maintained to ensure that they are effective for treating perchlorate.

Can I buy a home treatment device to remove perchlorate?
If you are concerned about perchlorate in your drinking water, you may consider purchasing a home treatment device such as a filter. However, in order to make a well-informed and cost-effective decision, consider checking with your water system to learn about the amount of perchlorate in your water and identifying a device that has been independently certified to remove perchlorate.

[HYPERLINK "http://www.nsf.org/consumer-resources/what-is-nsf-certification/water-filters-treatment-certification/contaminant-reduction-claims-guide" \t "_blank"], the [HYPERLINK "https://www.wqa.org/" \t "_blank"], [HYPERLINK "http://ul.com/" \t "_blank"] and [HYPERLINK "http://www.csagroup.org/global/en/services/testing-and-certification" \t "_blank"

] all certify home treatment products for removal of contaminants. The relevant perchlorate removal standard is [HYPERLINK "http://www.nsf.org/consumer-resources/health-and-safety-tips/water-quality-treatment-tips/standards-for-water-treatment-systems" \t "_blank"]. If you choose to use a home treatment device, it is very important to follow the manufacturer's operation and maintenance instructions carefully in order to make sure the device works properly.

Does perchlorate have a health advisory level?
Yes, on January 8, 2009, EPA released an interim drinking water health advisory of 15 parts of perchlorate for every billion parts of water (parts per billion or ppb).
For more information on the Interim Drinking Water Health Advisory for perchlorate can be found here: [HYPERLINK "http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P1004X7Q.txt"]

Has a safe level of exposure for perchlorate been established?
EPA has not yet established a maximum contaminant level goal for perchlorate. The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. On February 11, 2011, EPA determined that perchlorate meets the Safe Drinking Water Act criteria for regulation as a contaminant. The Agency found that perchlorate may have an adverse effect on the health of persons and is known to occur in public drinking water systems with a frequency and at levels that present a public health concern. Since that time, EPA has been reviewing the best available scientific data on a range of issues related to perchlorate in drinking water including its occurrence, treatment technologies, analytical methods and the costs and benefits of potential standards.

There also have been state actions on perchlorate such as standards, guidelines and advisories. In 2006, Massachusetts adopted a drinking water standard for perchlorate of 2 µg/L, and in 2007, California promulgated a standard of 6 µg/L. Twelve other states have established non-enforceable guidance, action or advisory levels. Depending on the state, a particular level may require a public water system to notify the public, serve as a screening tool for further action, or guide clean-up actions.

Customers that are served by a public water system can contact their local water supplier and ask for information on perchlorate in their drinking water.

PEER REVIEW QUESTIONS

Why is EPA conducting a peer review?
EPA will ask peer reviewers to comment on products that the agency will use to derive a Maximum Contaminant Level Goal (MCLG) for perchlorate. The MCLG is a non-enforceable goal defined under the Safe Drinking Water Act (SDWA) as “the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.” The MCLG is one of the considerations in developing the enforceable maximum contaminant level (MCL) for a regulated contaminant.

EPA believes that peer review is an important component of the scientific process. The critical feedback, suggestions, and new ideas provided by the peer reviewers stimulate creative thought, strengthen the interpretation of the reviewed material, and confer credibility on the product. The peer review objective is to provide advice to EPA on steps that will yield a highly credible scientific product that is supported by the scientific community.

Perchlorate Peer Review
Communications Plan

What products will be reviewed?
The agency, with contributions from Food and Drug Administration scientists, developed a model (also known as a Biologically Based Dose-Response model, or BBDR) to determine what concentrations of perchlorate affect the thyroid gland levels in infants and lactating mothers. Peer reviewers will be asked to comment on the Draft Biologically Based Dose-Response Model (BBDR), model code and draft model report entitled "Biologically Based Dose-Response Models for the Effect of Perchlorate on Thyroid Hormones in the Infant, Breast Feeding Mother, Pregnant Mother, and Fetus: Model Development, Revision, and Preliminary Dose-Response Analyses."

EPA also developed approaches for deriving a perchlorate MCLG by using relationships from published literature to connect the changes in thyroid hormones, as predicted by the BBDR model, to hypothyroxinemia (changes in thyroid gland levels) or development of the neurological system. Peer reviewers will be asked to comment on the draft report entitled "Peer Review Draft: Proposed Approach to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water."

Additionally, EPA is seeking comments on the peer review charge and the interim list of expert peer review panel candidates.

Where can I find the review products?
All documents in the docket are listed on the [HYPERLINK "http://www.regulations.gov"] website under Docket ID Numbers EPA-HQ-OW-2016-0438 and EPA-HQ-OW-2016-0439.

Can I provide comments on the review products?
Yes. The public will have an opportunity to review and comment on charge questions, the biologically based dose-response model and draft model report and the draft report describing application of the model to inform development of a perchlorate MCLG.

Additionally, we intend to allow for people to make brief statements during the peer review meeting. Also, any Safe Drinking Water Act regulation on perchlorate will be subject to public notice and comment.

How long is the comment period?
EPA announced that it is seeking public comments on two separate sets of materials. The first set is the interim list of peer review candidates and the draft charge. People should send their comments to Versar, Inc. no later than 30 days after publication in the Federal Register.

A companion notice, published on the same date, requests comments on the model, the draft model report and the draft report on application of the model to inform derivation of a perchlorate MCLG. People should send their comments to the docket no later than 60 days after publication in the Federal Register.

Will the review panelists see my comments?
EPA will provide panelists a summary of the public comments submitted on the draft products. Reviewers will also be given access to public comments submitted during the draft document's public comment period.

Perchlorate Peer Review
Communications Plan

When and where and will EPA hold the meeting?
The meeting is projected to occur during the fall/winter of 2016 (exact date to be determined). EPA will announce the meeting in the Federal Register at least 30 days in advance to provide the meeting date, location and registration information. EPA anticipates holding the two-day meeting in the Washington, DC metro area.

Why did EPA combine the two panel meetings?
EPA is conducting a combined panel meeting of the model, and application of the model to inform derivation of the perchlorate MCLG, to take advantage of efficiencies and to foster communication between all panelists.

What will EPA do with the public comments and panel recommendations?
The contractor will provide a peer review summary report to EPA containing the final comments and recommendations from the peer reviewers. EPA will make the final peer review report available to the public.

EPA will consider any public comments and peer reviewer comments submitted in accordance with the Federal Register notice when finalizing the products.

How did the contractor select the reviewers?
The contractor considered and screened all candidates against the selection criteria described in the March 1, 2016, and June 3, 2016, Federal Register notices (81 FR 10617 and 81 FR 35760, respectively) which included being free of any conflict of interest and available to participate in-person in a two-day peer review meeting in the Washington, DC area, during the projected fall/winter 2016 timeframe (exact date to be determined).

Following the screening process, the contractor narrowed the list of potential reviewers to 19 candidates. EPA is now soliciting comments on the interim list of 19 candidates.

What happens next?
Once the public comments on the interim list of candidates have been reviewed and considered, the contractor will select the final list of peer reviewers.

What happens after the peer reviewers are selected?
Following the selection process, the EPA will charge the peer reviewers with evaluating and providing written comments on the draft products. Additionally, peer reviewers will be provided a summary of public comments and given access to public comments submitted during the draft document's public comment period.

When will EPA establish a national drinking water standard for perchlorate?
EPA will consider public comments and peer reviewer comments submitted in accordance with the Federal Register notice when finalizing the peer review products. After the peer review is complete, EPA will take the next appropriate steps.

INTERNAL QUESTIONS AND ANSWERS

Perchlorate Peer Review
Communications Plan

What does EPA's data on perchlorate show?
The UCMR 1 perchlorate dataset is the best available nationally representative data on perchlorate occurrence in public water systems. Analytical detections of perchlorate at or above the minimum reporting level (4 µg/L) were identified in about 4% (155 of 3,865) of these systems. EPA estimates that between 5.1 million to 16.6 million people served by the sampled systems could be exposed to perchlorate in drinking water. While perchlorate analytical detections are fairly numerous and widespread geographically, the UCMR 1 findings indicate that perchlorate occurs at relatively low levels: about 85% of analytical perchlorate detections are less than 13 µg/L and 42% are less than 6 µg/L.

Why is it taking so long for us to regulate perchlorate?
In 2011, EPA announced its decision to regulate perchlorate under the Safe Drinking Water Act (SDWA).

In accordance with SDWA, the Agency requested EPA's Science Advisory Board (SAB) to review how to consider available data in deriving a Maximum Contaminant Level Goal (MCLG) for use in developing a perchlorate National Primary Drinking Water Regulation. The MCLG is a non-enforceable goal defined under the SDWA as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The MCLG is one of the considerations in developing the enforceable maximum contaminant level (MCL) for a regulated contaminant. The SAB released its final report on May 29, 2013 and recommended that EPA "derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling."

The agency, with contributions from Food and Drug Administration scientists, spent over two years to develop the model that accounts for population differences in iodide exposure and predicts changes in thyroid hormone levels that result from exposure to perchlorate.

Note: Following Section 1412(b)(1)(A), EPA is required to propose a perchlorate regulation by <u>February 11, 2013</u> (within 24 months of the determination to regulate), and a final regulation within 18 months of proposal.

Why did we combine the two separate peer review panel meetings into one?
EPA originally planned to conduct two separate peer review panels, starting with peer review of the model followed by a peer review of the MCLG report, including time between to make any necessary adjustments to the model. However, on February 18, 2016, NRDC filed a complaint in the U.S. District Court for the Southern District of N.Y. alleging that EPA failed to perform a nondiscretionary duty under SDWA (Section 1449(a)(2)) to propose and finalize a NPDWR for perchlorate. NRDC seeks court-ordered proposal and final deadlines; we are currently in settlement discussions with them.

In the meantime, in order to take advantage of efficiencies and to foster communication between all panelists, EPA is conducting a combined peer review panel meeting.

What is the status of the NRDC complaint?
NRDC filed a complaint in SDNY in February alleging failure to propose and finalize an MCLG and NPDWR for perchlorate as required by SDWA 1412(b)(1)(E). That section requires that, after EPA makes a determination to regulate a contaminant under SDWA, the Agency must propose such regulations within 24 months and finalize within 18 months (with opportunity for one 9—month extension).

Perchlorate Peer Review
Communications Plan

The status of the litigation is that we are negotiating a Consent Decree.

We have agreement on the following dates: proposal date of March 2018 and signature of the final action in July of 2019.

Current key difficulty is how to preserve our ability to withdraw the determination if the model demonstrates that outcome is appropriate (NRDC does not believe we have the authority to withdraw the determination to regulate). We haven't yet settled on how to propose addressing this issue.

Will the peer review products present alternative MCLGs?
No, the documents will not present alternative MCLGs, it presents methodologies for approaches to derive and MCLG. However some experts can be expected to predict the MCLGs that would result from using the methodologies that are described in the documents.

Will the methodologies that will be presented to the peer reviewers result in MCLGs that are in the range of MCLs set by California (6 µg/L) and Massachusetts (2 µg/L)?
Yes. Additionally, 12 states have guidance levels: AZ, FL, IL, KS, MD, NV, NJ, NM, NY, OR, TX, VT. The drinking water levels range from 1 to 18 µg/L. These levels may trigger public notice, serve as a screening tool for further action or guide cleanup action.

The use of the perchlorate model to inform the MCLG is precedent setting for the drinking water program.

> **How will this novel approach fit into the definition of an MCLG?**
> The MCLG is defined as the level at which no known or anticipated adverse effects on the health of persons occur and which allows an *adequate margin of safety*. It is a non-enforceable public health goal based on best available peer reviewed science. EPA will need to give consideration of the applicability of the approach to the definition of MCLG.
>
> **Since this is a novel approach, does EPA understand uncertainties and limitation?**
> Although EPA discusses uncertainties and limitations in the draft reports, because it is novel it brings with it new uncertainties and limitations that may not yet be fully understood.
>
> **How might this impact the program?**
> EPA believes that the perchlorate rulemaking effort is a unique action. Information on perchlorate toxicology is data rich and models existed prior to EPA undertaking the current effort. Model development and panel peer reviews for future drinking water regulations should be considered on a contaminant-by-contaminant basis.

What is our evaluation of perchlorate occurrence data?
Estimates of perchlorate occurrence in public water systems are key drivers for national costs and benefits. EPA's Unregulated Contaminant Monitoring Regulation 1 (UCMR 1) 2001-2005 is the best available nationally representative data.

- 4.1% of public water systems (155/3,865) reported at least 1 perchlorate detection ≥ 4 µg/L (the minimum reporting level)
- 5.1 M to 16.6 M people served by the sampled systems could be exposed to perchlorate from drinking water

However, commenters and workgroup members have pointed out limitations of UCMR 1 for estimating current occurrence. The minimum reporting level is 4 µg/L. Since UCMR 1 data has been collected 2 states have enacted perchlorate standards (CA & MA) and remediation activities or new sources of perchlorate may have impacted concentration levels in public water systems.
The US Chamber of Commerce challenged the UCMR1 occurrence data under the EPA's Information Quality Guidelines in 2012. For more information: **[HYPERLINK "https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration" \l "12004"]**

Are there any cross-office implications of promulgating a drinking water regulation?
Yes, promulgating a drinking water regulation for perchlorate would become the applicable or relevant and appropriate requirement (ARAR) and would replace the current preliminary remediation goal (PRG) for CERCLA sites (current PRG is based on the Interim Drinking Water Health Advisory level of 15 µg/L).

The OIG, SAB and others have recommended doing a cumulative health risk assessment for perchlorate, nitrate and other thyroid-disrupting chemicals. Shouldn't we have included these chemicals in the model and/or approach?
Doing a cumulative assessment of all of the thyroid-disrupting chemicals would lead to substantial delay in action for perchlorate. While EPA acknowledges that nitrate and thiocyanate have the same mode of action as perchlorate, and that the effects of multiple thyroid-disrupting chemicals can be additive, EPA does not believe there are sufficient scientific data currently available to assess and characterize the combined risk of these contaminants.

Is there an Environmental Justice/Equity component for the affected communities?
Each community faces unique challenges when addressing concerns related to environmental issues. Perchlorate in drinking water is related to localized sources of contamination often near where it is manufactured or produced. Currently, if water sampling results confirm that drinking water contains perchlorate at concentrations greater than 15 parts per billion, water systems should undertake additional sampling to assess the level, scope and localized source of contamination to inform next steps.

How will the RfD, or the interim health advisory, be used to inform the MCLG?
Based on SAB recommendations, EPA does not intend to use the perchlorate RfD to inform derivation of an MCLG. The SAB stated that it, ". . . recognizes that this is a novel approach as compared to previous MCLG derivations that use the RfD and exposure factors. However, PBPK/PDIUI modeling provides a more rigorous tool to integrate the totality of information available on perchlorate, and this approach may better address different life stage susceptibilities to perchlorate than the default MCLG approach."

Message

From: Christ, Lisa [Christ.Lisa@epa.gov]
Sent: 9/28/2016 1:09:43 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: FW: Perchlorate
Attachments: ROLL OUT Perchlorate Peer Review_9.27.16.docx

Hi Eric,
Let me know if you'd like me to make the phone calls tomorrow.
Lisa

From: Wadlington, Christina
Sent: Wednesday, September 28, 2016 8:29 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: Perchlorate

Just so you have it, provided is the most recent perchlorate roll out.

Can you confirm that SRMD will be conducting these notifications today?

- OGWDW notification to Regional Contacts (Christina)
- OPA notification to Regional PADS (OW)
- OGWDW notification to federal partners (SRMD)
    - HHS including ATSDR, NIEHS and FDA
    - DOD
    - NASA
- OPA calls to federal agencies' communications counterparts at HHS (ATSDR, FDA, NIEHS), DOD and NASA (OPA)

Christina Wadlington
Communications Director
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
Tel: 202.566.1859
Email: wadlington.christina@epa.gov
Webpage: www.epa.gov/safewater

Perchlorate Peer Review
Communications Plan

Pre-publication RELEASE DATE: September 29, 2016

ACTION: The agency is undertaking an independent, external panel peer review and announces the release of several materials for public comment that relate to EPA's Safe Drinking Water Act Decision Making on Perchlorate

KEY MESSAGES

- Perchlorate – a chemical used in rocket propellants and other applications – can disrupt the normal function of the thyroid gland in both children and adults.
- The agency is releasing peer review materials that relate to its SDWA decision making on perchlorate.
- Based on the recommendations made by EPA's Science Advisory Board, EPA and FDA developed a biologically-based dose response (BBDR) model that can be used to inform derivation of health based goals for drinking water. Previously, EPA used a reference-dose to establish EPA's interim health advisory level of 15 µg/L.
- The use of the BBDR model to inform decision making under the Safe Drinking Water Act is an important step forward, therefore EPA is conducting a transparent and rigorous expert peer review of the relevant science.
- After the peer review is complete, EPA will take the next appropriate steps.

ANTICIPATED REACTION

There is likely to be considerable interest and response to EPA's release of peer review materials and the peer review process itself. Over the past several years stakeholders have provided extensive comments on publically reviewable perchlorate materials and notices, met with EPA senior officials, managers and staff and have wrote the Administrator numerous letters.

EPA was recently sued by NRDC for the Agency's failure to issue proposed and final regulatory actions for perchlorate in accordance with the timelines provided in SDWA. EPA is currently negotiating with the petitioner to establish an agreeable schedule for development of the proposed action.

Stakeholders and the press are aware that EPA has been working to implement SAB recommendations and develop a BBDR model.

Stakeholders may be critical of the highly technical, underlying science to model perchlorate in sensitive life stages.

- Industry groups (Perchlorate Study Group, American Chemistry Council); drinking water utilities, the U.S. Chamber of Commerce and the Department of Defense will likely be critical of the underlying science
- Environmental groups will likely be critical of the underlying science
- Consumers, both those using public water systems and private wells, will be concerned about potential health risks from perchlorate
- Congressional interest – Senator Boxer

DESK STATEMENT

Perchlorate Peer Review
Communications Plan

To ensure the safety of drinking water for all Americans, EPA remains committed to completing the regulatory process for perchlorate in drinking water. In response to recommendations from our science advisors, the agency has developed new analyses to inform selection of a health based goal for the regulation. The agency is announcing the next steps in the peer review of these new analyses to ensure the agency's perchlorate regulatory decision-making is based on the best available science. EPA is also seeking public comment on the draft list of external peer review candidates, draft charge questions and draft biologically-based dose response (BBDR) model and BBDR accompanying report. The peer review panel is expected to meet early in 2017 in Washington, D.C.

Additional Background – HOLD unless need this level of technical detail
In 2011, EPA announced its decision to regulate perchlorate under the Safe Drinking Water Act (SDWA). In accordance with SDWA, the Agency requested EPA's Science Advisory Board (SAB) to review how to consider available data in deriving a Maximum Contaminant Level Goal (MCLG) for use in developing a perchlorate National Primary Drinking Water Regulation. The MCLG is a non-enforceable goal defined under the SDWA as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The MCLG is one of the considerations in developing the enforceable maximum contaminant level (MCL) for a regulated contaminant. The SAB released its final report on May 29, 2013 and recommended that EPA "derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling."

As recommended by the SAB, the agency, with contributions from FDA scientists, developed a BBDR model to determine under what conditions of iodine nutrition and exposure to perchlorate, that infants and lactating mothers would experience hypothyroxinemia (changes in thyroid hormone levels).

COMMUNICATIONS MATERIALS

External:

- Webpage (link will appear on https://www.epa.gov/dwstandardsregulations/perchlorate) will include:
    - Link to pre-pub FRN
    - Link to Draft BBDR model
    - BBDR model accompanying report
    - Peer review charge questions
    - Q&A (See marked Q&A below)
- Q&A (Consumer and Peer Review)
- Fact Sheet (developed from marked Q&A below)

Internal:

- Communications Plan with Roll out schedule
- Notification List
- Q&A

RELEASE SCHEDULE

September 27, 2016

- Federal Agency Briefing (OGWDW)

Perchlorate Peer Review
Communications Plan

September 28, 2016

- OGWDW notification to Regional Contacts
- OPA notification to Regional PADS
- OGWDW notification to federal partners
    - HHS including ATSDR, NIEHS and FDA
    - DOD
    - NASA
- OPA calls to federal agencies' communications counterparts at HHS (ATSDR, FDA, NIEHS), DOD and NASA

September 29, 2016

9:00 a.m	Begin head's up calls to stakeholder list below
10:00 a.m	Congressional heads up emails
12:00 p.m	Website goes live – Broader congressional notifications (emails with link to website)
1:00 p.m	Social media and stakeholder notification via email (Water Headlines listserv)

STAKEHOLDER NOTIFICATION

OGWDW:

- Michael Deane, Director, National Association of Water Companies
- Tracy Mehan, Government Affairs Director, American Water Works Association
- Mike Paque, Executive Director, Groundwater Protection Council
- Jim Taft, Executive Director, Association of State Drinking Water Administrators
- Lynn Thorp, National Campaigns Director, Clean Water Action
- Diane Van de Hei, Executive Director, Association of Metropolitan Water Agencies
- Sam Wade, Executive Director, National Rural Water Association

OLEM (OSRTI):

- Association of State and Territorial Solid Waste Management Officials

EXTERNAL & INTERNAL QUESTIONS AND ANSWERS

EXTERNAL CONSUMER QUESTIONS- for Website and/or Fact Sheet

Where is perchlorate found? (website and fact sheet)

Perchlorate occurs naturally in arid states in the Southwest United States, in nitrate fertilizer deposits in Chile, and in potash ore in the United States and Canada. It also forms naturally in the atmosphere. Perchlorate can be manufactured and used as an industrial chemical and can be found in rocket propellant, explosives, fireworks and road flares. It has also been found in some public drinking water systems and in food.

Why is perchlorate in drinking water a health concern? (website and fact sheet)

Perchlorate can disrupt the normal function of the thyroid gland in both children and adults. In adults, the thyroid plays an important role in metabolism, making and storing hormones that help regulate the heart rate, blood pressure, body temperature, and the rate at which food is converted into energy. In fetuses and infants, thyroid hormones are critical for normal growth and development of the central nervous system. Perchlorate can interfere with the human body's ability to absorb iodine into the thyroid gland which is a critical element in the production of thyroid hormones.

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How does perchlorate get into my drinking water? (website and fact sheet)
Perchlorate dissolves easily, is relatively stable and is mobile in water. While it has often been detected in water supplies in close proximity to sites where solid rocket fuel is manufactured or used, there are also locations in the United States lacking a clearly defined source.

Besides drinking water, how else can people be exposed to perchlorate? (website and fact sheet)
People are exposed to perchlorate primarily through eating contaminated food or drinking water. The Food and Drug Administration (FDA) Total Diet Study combines nationwide sampling and analysis of hundreds of food items along with national surveys of food intake to develop comprehensive dietary exposure estimates for a variety of demographic groups in the U.S. In the 2005-2006 survey the FDA found detectable levels of perchlorate in 74 percent of the foods sampled. The complete set of FDA perchlorate data can be found here: [HYPERLINK "http://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm077685.htm"]

How do I know if perchlorate is in my water? (website and fact sheet)
Contact your local water supplier to find out if perchlorate is in your drinking water and what steps your utility is taking to reduce your exposure If you don't know who your local water supplier is, the information should be included in your latest water bill.

Can perchlorate be boiled out of my water? (website and fact sheet)
No, perchlorate cannot be removed by heating or boiling water.

How does a utility reduce/remove perchlorate? (website and fact sheet)
A number of options are available to drinking water systems to lower concentrations of perchlorate in the drinking water supply. In some cases, drinking water systems may be able to reduce concentrations of perchlorate by closing contaminated wells or changing rates of blending of water sources.

Perchlorate can be removed using a number of advanced treatment technologies. Each technology has advantages and disadvantages depending on the level of perchlorate present in the source water, removal goals, other water quality parameters, competing treatment objectives, and treatment waste disposal options. Regenerable and single-pass ion exchange, reverse osmosis, and fixed- and fluidized-bed biological treatment can all remove perchlorate from drinking water sources.

These treatment technologies are used by some public water systems today and should be carefully designed and maintained to ensure that they are effective for treating perchlorate.

I get my tap water from a private well. How can I find out if perchlorate is in my water? (website and fact sheet)
If you are concerned about the possibility of perchlorate in your drinking water and you are served by a private well, EPA recommends testing your drinking water. Approved laboratories can analyze a sample of your water to determine whether perchlorate is present and at what concentrations. More information about private wells can be found here: [HYPERLINK "http://www.epa.gov/privatewells" \h].

Why did EPA decide to regulate perchlorate? (website)

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The Safe Drinking Water Act (SDWA) requires that once every five years, EPA issue a Contaminant Candidate List (CCL). The CCL is a list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations, but are known or anticipated to occur in public water systems. Perchlorate was a part of CCL1 (1998), CCL2 (2005) and CCL3 (2009). In addition, EPA issues an Unregulated Contaminant Monitoring Rule (UCMR) to identify up to 30 unregulated contaminants to be monitored by large public water systems (PWSs) and a subset of small PWSs across the U.S. The UCMR provides EPA and other interested parties with nationally representative data on the occurrence of particular contaminants in drinking water. This data set lets the Agency assess the number of people potentially being exposed and provides an estimate of the levels of that exposure. Perchlorate was included in UCMR 1 (2001- 2005).

After issuing a CCL, EPA must decide whether to regulate at least five or more contaminants on the list (called Regulatory Determination). A Regulatory Determination is a formal decision on whether (or not) EPA should initiate a rulemaking process to develop a regulation for a specific contaminant or group of contaminants. In 2011, EPA announced its decision to regulate perchlorate under the Safe Drinking Water Act (SDWA). Specifically, EPA determined that perchlorate meets SDWA's criteria for regulating a contaminant--that is, perchlorate may have an adverse effect on the health of persons; perchlorate is known to occur or there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern; and in the sole judgment of the Administrator, regulation of perchlorate in drinking water systems presents a meaningful opportunity for health risk reduction for person served by public water systems.

Why is it taking so long for EPA to regulate perchlorate? (website)
In 2011, as required by SDWA, EPA sought recommendations from its Science Advisory Board on how to derive a health based MCLG prior to proposing a perchlorate regulation. SAB recommend an approach to evaluating health effects for the MCLG different from the one on which EPA had based its decision to regulate perchlorate. The SAB recommended EPA undertake development of a model to predict thyroid hormone changes that result from exposure to perchlorate. Since 2013, FDA and EPA scientists have been developing a model consistent with SAB recommendations to determine under what conditions of iodine nutrition and perchlorate exposure across sensitive lifestages would experience low serum free and total thyroxine (hypothyroxinemia). Currently, EPA is undertaking an expert panel peer review of scientific products recommended by the SAB. EPA expects to hold the peer review panel meeting in early 2017. After the peer review is complete, EPA will take the next appropriate steps.

Why can't EPA just come up with an enforceable MCL? Why create a non-enforceable MCLG first?
When developing a National Primary Drinking Water Regulation (NPDWR), EPA must establish a maximum contaminant level goal (MCLG). The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. Once the MCLG is determined, EPA sets an enforceable standard (in most cases, a maximum contaminant level or MCL) as close to the MCLG as feasible, taking cost into consideration. The MCL is the maximum level allowed of a contaminant in water which is delivered to any user of a public water system. The peer review materials will assist EPA with establishing an MCLG so that the Agency can then identify an enforceable MCL.

The peer review materials will assist EPA with establishing an MCLG. However, if EPA determines that a NPDWR for perchlorate is required, EPA will also establish an enforceable MCL at the same time.

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Has a safe level of exposure for perchlorate been established? (website)
EPA has not yet established a maximum contaminant level goal for perchlorate. The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. On February 11, 2011, EPA determined that perchlorate meets the Safe Drinking Water Act criteria for regulation as a contaminant. The Agency found that perchlorate may have an adverse effect on the health of persons and is known to occur in public drinking water systems with a frequency and at levels that present a public health concern. Since that time, EPA has been reviewing the best available scientific data on a range of issues related to perchlorate in drinking water including its occurrence, treatment technologies, analytical methods and the costs and benefits of potential standards.

There also have been state actions on perchlorate such as standards, guidelines and advisories. In 2006, Massachusetts adopted a drinking water standard for perchlorate of 2 µg/L, and in 2007, California promulgated a standard of 6 µg/L. Twelve other states have established non-enforceable guidance, action or advisory levels. Depending on the state, a particular level may require a public water system to notify the public, serve as a screening tool for further action, or guide clean-up actions.

Customers that are served by a public water system can contact their local water supplier and ask for information on perchlorate in their drinking water.

EXTERNAL PEER REVIEW Q&A:

Why is EPA conducting a peer review? (website)
EPA will ask peer reviewers to comment on products that the agency will use to derive a Maximum Contaminant Level Goal (MCLG) for perchlorate. The MCLG is a non-enforceable goal defined under the Safe Drinking Water Act (SDWA) as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The MCLG is one of the considerations in developing the enforceable maximum contaminant level (MCL) for a regulated contaminant.

EPA believes that peer review is an important component of the scientific process. The critical feedback, suggestions, and new ideas provided by the peer reviewers stimulate creative thought, strengthen the interpretation of the reviewed material, and confer credibility on the product. The peer review objective is to provide advice to EPA on steps that will yield a highly credible scientific product that is supported by the scientific community.

Where can I find the review products? (website)
All documents in the docket are listed on the [HYPERLINK "http://www.regulations.gov"] website under Docket ID Numbers EPA-HQ-OW-2016-0438 and EPA-HQ-OW-2016-0439.

Can I provide comments on the review products? (website)
Yes. The public will have an opportunity to review and comment on charge questions and the draft reports undergoing review. Additionally, we intend to allow for people to make brief statements during the peer review meeting. Also, any Safe Drinking Water Act regulation on perchlorate will be subject to public notice and comment.

Are there other reports that will be peer reviewed before EPA proposes a regulation?

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Yes after the peer review of the BBDR report is complete, the Agency plans to conduct peer review of another report that describes methodologies for deriving a Maximum Contaminant Level Goal (MCLG Report) for using the BBDR model. EPA plans to consider the peer review comments on the BBDR model before we present this next MCLG report for peer review. We expect peer review of the MCLG Report will take place in the spring of 2017.

When will EPA establish a national drinking water standard for perchlorate? (website and/or fact sheet)
EPA will consider public comments and peer reviewer comments submitted in accordance with the Federal Register notice when finalizing the peer review products. After the peer review is complete, EPA will take the next appropriate steps.

INTERNAL CONSUMER Q&As:

Have public drinking water systems been sampled for perchlorate?
Both California and Massachusetts have drinking water regulations in place for perchlorate and extensive drinking water samples have been collected in those states. EPA included perchlorate in the first unregulated contaminant monitoring rule and a robust national sampling effort was conducted through the implementation of that rule. The sampling results are available on EPA's website at https://www.epa.gov/dwucmr/first-unregulated-contaminant-monitoring-rule. Customers served by a public water system can contact their local water supplier and ask if they test for perchlorate. If you are concerned about the possibility of perchlorate in your drinking water and you are served by a private well, EPA recommends testing your drinking water. In addition, EPA recommends that residents reach out to their local public health department for more information. More information about private wells can be found here: [HYPERLINK "http://www.epa.gov/privatewells" \h].

Should I be worried about making infant formula with tap water? [refer to FDA]

Should I consider taking iodine dietary supplements if I am worried about perchlorate? [refer to FDA]

Can I buy a home treatment device to remove perchlorate?
If you are concerned about perchlorate in your drinking water, you may consider purchasing a home treatment device such as a filter. However, in order to make a well-informed and cost-effective decision, consider checking with your water system to learn about the amount of perchlorate in your water and identifying a device that has been independently certified to remove perchlorate.

[HYPERLINK "http://www.nsf.org/consumer-resources/what-is-nsf-certification/water-filters-treatment-certification/contaminant-reduction-claims-guide" \t "_blank"], the [HYPERLINK "https://www.wqa.org/" \t "_blank"], [HYPERLINK "http://ul.com/" \t "_blank"] and [HYPERLINK "http://www.csagroup.org/global/en/services/testing-and-certification" \t "_blank"] all certify home treatment products for removal of contaminants. The relevant perchlorate removal standard is [HYPERLINK "http://www.nsf.org/consumer-resources/health-and-safety-tips/water-quality-treatment-tips/standards-for-water-treatment-systems" \t "_blank"]. If you choose to use a home treatment device, it is very important to follow the manufacturer's operation and maintenance instructions carefully in order to make sure the device works properly.

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INTERNAL PEER REVIEW QUESTIONS

What products will be reviewed?
The agency, with contributions from Food and Drug Administration scientists, developed a model (also known as a Biologically Based Dose-Response model, or BBDR) to determine what concentrations of perchlorate affect the thyroid gland levels in infants and lactating mothers. Peer reviewers will be asked to comment on the Draft Biologically Based Dose-Response Model (BBDR), model code and draft model report entitled "Biologically Based Dose-Response Models for the Effect of Perchlorate on Thyroid Hormones in the Infant, Breast Feeding Mother, Pregnant Mother, and Fetus: Model Development, Revision, and Preliminary Dose-Response Analyses."

Additionally, EPA is seeking comments on the peer review charge and the interim list of expert peer review panel candidates.

Why did EPA change its plans to conduct peer review of two reports at the same time?
EPA previously announced that we planned to conduct peer review of both the BBDR model and a report on methodologies for developing a perchlorate MCLG to achieve efficiency. EPA has reevaluated that approach in response to concerns that a simultaneous review of the methodology to develop a perchlorate MCLG would not allow the Agency to consider peer reviewer comments on the draft BBDR model prior to using the model to evaluate alternative methodologies to derive an MCLG. Today's notice therefore seeks input only on the peer review of the model, not its application. EPA will seek input on a second peer review of the application of the model to inform development of a perchlorate MCLG in a future notice.

How long is the comment period?
EPA announced that it is seeking public comments on two separate sets of materials. The first set is the interim list of peer review candidates and the draft charge. People should send their comments to Versar, Inc. no later than 21 days after publication in the Federal Register.

A companion notice, published on the same date, requests comments on the model and the draft model report. People should send their comments to the docket no later than 45 days after publication in the Federal Register.

Will the review panelists see my comments?
EPA will provide panelists a summary of the public comments submitted on the draft products. Panelists will also be given access to public comments submitted during the draft document's public comment period.

When and where and will EPA hold the meeting?
The meeting is projected to occur early in 2017 (exact date to be determined). EPA will announce the meeting in the Federal Register at least 30 days in advance to provide the meeting date, location and registration information. EPA anticipates holding the two-day meeting in the Washington, DC metro area.

What will EPA do with the public comments and panel recommendations?

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EPA will provide panelists a summary of the public comments submitted on the draft products. Panelists will also be given access to public comments submitted during the draft document's public comment period.

The contractor will provide a peer review summary report to EPA containing the final comments and recommendations from the panel of peer reviewers. EPA will make the final peer review report available to the public.

EPA will consider any public comments and peer reviewer comments submitted in accordance with the Federal Register notice when finalizing the products.

How did the contractor select the reviewers?
The contractor considered and screened all candidates against the selection criteria described in the March 1, 2016, and June 3, 2016, Federal Register notices (81 FR 10617 and 81 FR 35760, respectively) which included being free of any conflict of interest and available to participate in-person in a two-day peer review meeting in the Washington, DC area, during the projected fall/winter 2016 timeframe (exact date to be determined).

Following the screening process, the contractor narrowed the list of potential reviewers to 19 candidates. EPA is now soliciting comments on the interim list of 19 candidates.

What happens next?
Once the public comments on the interim list of candidates have been reviewed and considered, the contractor will select the final list of peer reviewers.

What happens after the peer reviewers are selected?
Following the selection process, the EPA will charge the peer reviewers with evaluating and providing written comments on the draft products. Additionally, peer reviewers will be provided a summary of public comments and given access to public comments submitted during the draft document's public comment period.

INTERNAL POLICY & DATA QUESTIONS AND ANSWERS:

What does EPA's data on perchlorate show?
The UCMR 1 perchlorate dataset is the best available nationally representative data on perchlorate occurrence in public water systems. Analytical detections of perchlorate at or above the minimum reporting level (4 µg/L) were identified in about 4% (155 of 3,865) of these systems. EPA estimates that between 5.1 million to 16.6 million people served by the sampled systems could be exposed to perchlorate in drinking water.

Why doesn't EPA require a contaminant to be monitored under more than one UCMR cycle?
Through each UCMR cycle, EPA anticipates a sufficient set of national monitoring data will be collected to properly characterize the level and frequency of occurrence in drinking water. Generally speaking, particular contaminants are not included in multiple UCMR cycles. Any decisions regarding future compliance monitoring will depend on the outcome of EPA's regulatory determination process. In the meantime, it is possible that particular states will establish additional unregulated contaminant

monitoring requirements or recommendations for specific contaminants. PWSs are responsible for being aware of and complying with any state requirements.

What is the status of the NRDC complaint? [Reviewed by OGC]
NRDC filed a complaint in SDNY in February alleging failure to propose and finalize an MCLG and NPDWR for perchlorate as required by SDWA 1412(b)(1)(E). That section requires that, after EPA makes a determination to regulate a contaminant under SDWA, the Agency must propose such regulations within 24 months and finalize within 18 months (with opportunity for one 9—month extension).
EPA and NRDC are discussing how to proceed with the litigation.

What is our evaluation of perchlorate occurrence data?
Estimates of perchlorate occurrence in public water systems are key drivers for national costs and benefits. EPA's Unregulated Contaminant Monitoring Regulation 1 (UCMR 1) 2001-2005 is the best available nationally representative data.

- 4.1% of public water systems (155/3,865) reported at least 1 perchlorate detection ≥ 4 µg/L (the minimum reporting level)
- 5.1 M to 16.6 M people served by the sampled systems could be exposed to perchlorate from drinking water

However, commenters have pointed out limitations of UCMR 1 for estimating current occurrence. The minimum reporting level is 4 µg/L. Since UCMR 1 data has been collected 2 states have enacted perchlorate standards (CA & MA) and remediation activities or new sources of perchlorate may have impacted concentration levels in public water systems. The US Chamber of Commerce challenged the UCMR1 occurrence data under the EPA's Information Quality Guidelines in 2012. For more information: [HYPERLINK "https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration" \l "12004"]

Are there any cross-office implications of promulgating a drinking water regulation?
Yes, potentially. Consistent with CERCLA section 121 and the National Contingency Plan, a promulgated drinking water MCL for perchlorate may be considered as a potential ARAR ("applicable or relevant and appropriate requirement"), depending on site-specific circumstances. Once promulgated, an MCL normally would be used instead of a Drinking Water Health Advisory for CERCLA response selection and implementation purposes (e.g., establishing a preliminary remediation goal and cleanup level).

The OIG and others have recommended doing a cumulative health risk assessment for perchlorate, nitrate and other thyroid-disrupting chemicals. Shouldn't we have included these chemicals in the model and/or approach?
Doing a cumulative assessment of all of the thyroid-disrupting chemicals would lead to substantial delay in action for perchlorate. While EPA acknowledges that nitrate and thiocyanate have the same mode of action as perchlorate, and that the effects of multiple thyroid-disrupting chemicals can be additive, EPA does not believe there are sufficient scientific data currently available to assess and characterize the combined risk of these contaminants.

Is there an Environmental Justice/Equity component for the affected communities?
Each community faces unique challenges when addressing concerns related to environmental issues. Perchlorate in drinking water is related to localized sources of contamination often near where it is

manufactured or used. Currently, if water sampling results confirm that drinking water contains perchlorate at concentrations greater than 15 μg/L, water systems should undertake additional sampling to assess the level, scope and localized source of contamination to inform next steps.

How will the RfD, or the interim health advisory, be used to inform the MCLG?
Based on SAB recommendations, EPA does not intend to use the perchlorate RfD to inform derivation of an MCLG. The SAB stated that it, ". . . recognizes that this is a novel approach as compared to previous MCLG derivations that use the RfD and exposure factors. However, PBPK/PDIUI modeling provides a more rigorous tool to integrate the totality of information available on perchlorate, and this approach may better address different life stage susceptibilities to perchlorate than the default MCLG approach."

Does perchlorate have a health advisory level?
Yes, on January 8, 2009, EPA released an interim drinking water health advisory of 15 parts of perchlorate for every billion parts of water (parts per billion or ppb) also referred to as 15 μg/L. EPA continues to evaluate the health effects of perchlorate and we anticipate that this interim drinking water health advisory may be re-evaluated as part of EPA's regulatory development process. For more information on the Interim Drinking Water Health Advisory for perchlorate can be found here: [HYPERLINK "http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P1004X7Q.txt"]

Can a person drink tap water containing perchlorate at or below the level of the health advisory every day of their life and not expect adverse health effects from these chemicals?
No, the Interim Subchronic Drinking Water Health Advisory of 15 micrograms per liter (μg/L), issued in December 2008, was derived to be protective of pregnant women for effects that can last a lifetime. The perchlorate interim subchronic HA covers a period of more than 30 days, but less than a year.

Appointment

From: Anderson, Denise [anderson.denise@epa.gov]
Sent: 7/28/2016 8:48:19 PM
To: Beauvais, Joel [Beauvais.Joel@epa.gov]; Grevatt, Peter [Grevatt.Peter@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Olson, Daniel [Olson.Daniel@epa.gov]; Burke, Thomas [Burke.Thomas@epa.gov]; Vaught, Laura [Vaught.Laura@epa.gov]; Mitchell, Stacey [Mitchell.Stacey@epa.gov]; Neugeboren, Steven [Neugeboren.Steven@epa.gov]
CC: Townsend, Clifton [Townsend.Clifton@epa.gov]; Perkinson, Russ [Perkinson.Russ@epa.gov]; Helm, Erik [Helm.Erik@epa.gov]; Georges, Jessica [Georges.Jessica@epa.gov]; Greene, Ashley [Greene.Ashley@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]; Threet, Derek [Threet.Derek@epa.gov]; Hafez, Ahmed [Hafez.Ahmed@epa.gov]

Subject: Perchlorate in Drinking Water
Attachments: Perchlorate in Drinking Waterv4 7-28-16.pptx
Location: WJC-N 3412

Start: 8/1/2016 8:30:00 PM
End: 8/1/2016 9:00:00 PM
Show Time As: Tentative

Perchlorate in
Drinking Waterv4...

Point of Contact for the Meeting: Lisa Christ 202-564-8354
SCt: Denise Anderson, 564-1782

Purpose: To provide background information on EPA's activities related to the development of a National Primary Drinking Water Regulation for Perchlorate and peer review of scientific reports.

Background: In February, 2011 EPA published a determination to regulate perchlorate in drinking water. In 2012, EPA sought recommendations from SAB on how to derive a MCLG for perchlorate in accordance with SDWA. To address SAB recommendations, EPA and FDA scientist worked collaboratively to develop a Biologically Based Dose-Response model (PBPK model) to inform the derivation of a Maximum Contaminant Level Goal (MCLG) for perchlorate. EPA will conduct an expert peer review of the model, model report and report describing approaches to derive an MCLG in late 2016. EPA will convene a combined peer review process to take advantage of efficiencies and in response to a lawsuit filed by NRDC alleging EPA failed to propose and finalize a NPDWR for perchlorate by the statutory deadline.

EPA Staff (Required): Stan Meiburg, Joel Beauvais, Peter Grevatt, Eric Burneson, Lisa Christ, Daniel Olson, Tom Burke, Laura Vaught

EPA Staff (Optional): Clifton Townsend, Samuel Hernandez-Quinones, Russ Perkinson, Erik Helm, Jessica Georges. Ashley Greene, Ann Campbell

Message

From: Wadlington, Christina [Wadlington.Christina@epa.gov]
Sent: 7/21/2016 10:22:42 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: RE: TPs on perchlorate for Joel
Attachments: Perchlorate_TPs for Joel.cw.docx

Here are some edits to consider to make it a bit more user friendly. Sorry it's a lot of red....

Christina Wadlington
Communications Director
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
Tel: 202.566.1859
Email: wadlington.christina@epa.gov
Webpage: www.epa.gov/safewater

From: Burneson, Eric
Sent: Thursday, July 21, 2016 5:16 PM
To: Wadlington, Christina <Wadlington.Christina@epa.gov>
Subject: RE: TPs on perchlorate for Joel

No but its for Joel to explain to the Administrator what we are doing.

From: Wadlington, Christina
Sent: Thursday, July 21, 2016 5:15 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Re: TPs on perchlorate for Joel

I was going to ask, this is supposed to be for the general public?

Sent from my iPhone

On Jul 21, 2016, at 5:08 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

> It need a lot of work. Way too technical.
>
> ---
>
> **From:** Wadlington, Christina
> **Sent:** Thursday, July 21, 2016 5:06 PM
> **To:** Burneson, Eric <Burneson.Eric@epa.gov>
> **Subject:** Re: TPs on perchlorate for Joel
>
> Ok thanks. I'll send any comments or edits shortly.
>
> Sent from my iPhone
>
> On Jul 21, 2016, at 4:52 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

FYI I am starting to review and revise these now.

From: Christ, Lisa
Sent: Thursday, July 21, 2016 4:52 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: TPs on perchlorate for Joel

<Perchlorate_TPs for Joel.docx>

Perchlorate

Peer Review of BBDR Model, Model Report and Approach to Derive an MCLG

Key Messages:

- The BBDR model will allow EPA to predict the effects of perchlorate on thyroid levels in lactating mothers and infants
- The use of a BBDR model to inform NPDWR development is a novel, precedent setting approach; the RfD would no longer represent the best available science.
- Both the model and the approach to derive an MCLG for perchlorate will undergo a transparent and rigorous expert peer review process.
- The EPA intends to link the ~~BBDR~~ model ~~output for thyroid hormone perturbations through~~ through(?) epidemiology studies to health end points.
- The EPA's peer review documents will not include ~~intends to present more than one approach for peer review;~~ potential associated perchlorate concentrations ~~will not be provide~~d. However, experts ~~can~~ will be able to estimate a potential MCLG using the report and other information (RSC, exposure factors, etc)
- The potential associated perchlorate concentrations are within the range of perchlorate values already publically available.
  - FRN for positive regulatory determination 4, 6, 9, 13, 14, 19 ug/L
  - Interim Health Advisory 15 ug/L
  - California's MCL 6 ug/L; Massachusetts MCL 2 ug/L

Commented [CW1]: Does this mean the RfD is no longer relevant?

Biological Based Dose-Response (BBDR) Model & Report

- The BBDR model was developed in collaboration with FDA scientists ~~by integrating physiologically based pharmacokinetic (PBPK) models for perchlorate and iodide with BBDR models for thyroid hormones~~ to predict the effect of perchlorate on the thyroid gland in lactating women, formula-fed and breast-fed infants ~~for the postnatal period from days 7 to 90.~~
- ~~The model is focused on the condition of hypothyroxinemia as a more appropriate indicator of the potential adverse health effects of perchlorate as recommended by the SAB.~~
- The model predicts the effects of perchlorate on thyroid levels, specifically serum thyroid hormone concentrations (fT4), ~~in the lactating mother exposed to perchlorate in the diet and in infants exposed via ingestion of perchlorate in formula or breast milk.~~
- ~~The model output is fT4 levels~~ at different iodine nutrition levels and various levels of exposure to perchlorate ~~exposure.~~
- The model report will describe~~s~~ the model development and how parameters are selected. It will also provide ~~parameterization,~~ the effectiveness of the model when compared to empirical data (true?) ~~model calibration and results,~~ dose-response evaluation and the sensitivity analysis.

Approach to Derive an MCLG

- The BBDR model output for fT4 is based on a third trimester pregnant woman, however, the first trimester is more critical since ~~alterations~~ changes to~~in~~ thyroid hormone levels during the first trimester are ~~the most important in regard to~~can affect neurodevelopmental ~~outcomes~~

- Therefore, ~~S~~studies that considered ~~perturbations~~ changes in ~~in~~ thyroid hormones in the first trimester pregnant mothers that showed ~~relating to~~ adverse neurodevelopmental ~~outcome in her offspring were identified~~effects to her infant were used.
- In order to connect the BBDR output to the literature, the EPA derived a distribution for ft4 levels for first trimester mothers ~~fT4 levels based on the literature for pregnant mothers with normal iodine levels (200 ug/L).~~
- ~~The distribution was shifted to account for low maternal iodine (100 ug/L) by 14% as estimated by the BBDR model.~~
- ~~T~~Two endpoints are being evaluated:
    - ~~To evaluate the impact of the shift in fT4 for each dose of perchlorate, the EPA defined a baseline from the literature to estimate two subcomponents of the~~ The percent change in Bayley Scales of Infant and Toddler Development [the Psychomotor Development Index (PDI)/Mental Development Index (MDI)] scores ~~for the offspring of an individual with mildly deficient iodine intake at the 10th percentile for fT4 with no perchlorate exposure. Next, the Agency calculated the percentage change in PDI and MDI~~ at each dose of perchlorate ~~from the baseline PDI/MDI.~~
    - ~~EPA also evaluated t~~The shift in the percentage of pregnant women and infant populations ~~the sensitive lifestages (e.g., pregnant mothers, infants)~~ with hypothyroxinemia upon exposure to perchlorate ~~under iodide deficient conditions~~ as determined by BBDR model output.

Anticipated Stakeholder Reaction:

- There is likely to be considerable interest and response to EPA's release of peer review materials and the peer review process itself. Over the past several years stakeholders have provided extensive comments on publically reviewable perchlorate materials and notices, met with EPA senior officials, managers and staff and have wrote the Administrator numerous letters.
- Stakeholders and the press are aware that EPA has been working to implement SAB recommendations and develop and BBDR model and approach to inform development of an MCLG.
- Stakeholder's response will generally be critical of the highly technical, underlying science to model perchlorate in sensitive lifestages and application of the model output to inform derivation of a perchlorate MCLG.
    - Industry groups (Perchlorate Study Group, American Chemistry Council); drinking water utilities, the U.S. Chamber of Commerce and the Department of Defense will likely be critical of the underlying science and that the peer review process was expedited.
    - Environmental groups will likely be critical of the underlying science.
    - Consumers, both those using public water systems and private wells, will be concerned about potential health risks from perchlorate.

Requesting Peer Review Input On Appropriateness of:

- Selection of studies to set model parameters
- Selection of fT4 value to define hypothyroxinemia
- Selection of 5% increase in the proportion of individuals deemed hypothyroxinemic
- Selection of PDI/MDI as end point
- Selection of 1% change in Bayleys Scales of Infant Development (PDI/MDI) as threshold
- Selection of 100 ug/day iodine nutrition level

Message

From: Christ, Lisa [Christ.Lisa@epa.gov]
Sent: 7/21/2016 8:51:54 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: TPs on perchlorate for Joel
Attachments: Perchlorate_TPs for Joel.docx

Perchlorate

Peer Review of BBDR Model, Model Report and Approach to Derive an MCLG

Key Messages:

- ➢ The use of a BBDR model to inform NPDWR development is a novel, precedent setting approach; the RfD would no longer represent the best available science.
- ➢ Both the model and the approach to derive an MCLG for perchlorate will undergo a transparent and rigorous expert peer review process.
- ➢ The EPA intends to link the BBDR model output for thyroid hormone perturbations through epidemiology studies to health end points.
- ➢ The EPA intends to present more than one approach for peer review; potential associated perchlorate concentrations will not be provided. However, experts can estimate potential MCLG using the report and other information (RSC, exposure factors, etc)
- ➢ The potential associated perchlorate concentrations are within the range of perchlorate values already publically available.
    - FRN for positive regulatory determination 4, 6, 9, 13, 14, 19 ug/L
    - Interim Health Advisory 15 ug/L
    - California's MCL 6 ug/L; Massachusetts MCL 2 ug/L

Biological Based Dose-Response (BBDR) Model & Report

- The BBDR model was developed in collaboration with FDA scientists by integrating physiologically based pharmacokinetic (PBPK) models for perchlorate and iodide with BBDR models for thyroid hormones to predict the effect of perchlorate on the thyroid gland in lactating women, formula-fed and breast-fed infants for the postnatal period from days 7 to 90.
- The model is focused on the condition of hypothyroxinemia as a more appropriate indicator of the potential adverse health effects of perchlorate as recommended by the SAB.
- The model predicts the effects of perchlorate on serum thyroid hormone concentrations (fT4) in the lactating mother exposed to perchlorate in the diet and in infants exposed via ingestion of perchlorate in formula or breast milk.
- The model output is fT4 levels at different iodine nutrition levels and perchlorate exposure.
- The model report describes the model development and parameterization, model calibration and results, dose-response evaluation and the sensitivity analysis.

Approach to Derive an MCLG

- The BBDR model output for fT4 is based on a third trimester pregnant woman, however, the first trimester is more critical since alterations in thyroid hormone levels during the first trimester are the most important in regard to neurodevelopmental outcomes
- Studies that considered perturbations in thyroid hormones in the first trimester pregnant mothers relating to adverse neurodevelopmental outcome in her offspring were identified.
- In order to connect the BBDR output to the literature, the EPA derived a distribution for first trimester fT4 levels based on the literature for pregnant mothers with normal iodine levels (200 ug/L).
- The distribution was shifted to account for low maternal iodine (100 ug/L) by 14% as estimated by the BBDR model.

- Two endpoints are evaluated:
  - To evaluate the impact of the shift in fT4 for each dose of perchlorate, the EPA defined a baseline from the literature to estimate two subcomponents of the Bayley Scales of Infant and Toddler Development [the Psychomotor Development Index (PDI)/Mental Development Index (MDI)] scores for the offspring of an individual with mildly deficient iodine intake at the 10th percentile for fT4 with no perchlorate exposure. Next, the Agency calculated the percentage change in PDI and MDI at each dose of perchlorate from the baseline PDI/MDI.
  - EPA also evaluated the shift in the percentage of the sensitive lifestages (e.g., pregnant mothers, infants) with hypothyroxinemia upon exposure to perchlorate under iodide deficient conditions as determined by BBDR model output.

<u>Anticipated Stakeholder Reaction:</u>

- There is likely to be considerable interest and response to EPA's release of peer review materials and the peer review process itself. Over the past several years stakeholders have provided extensive comments on publically reviewable perchlorate materials and notices, met with EPA senior officials, managers and staff and have wrote the Administrator numerous letters.
- Stakeholders and the press are aware that EPA has been working to implement SAB recommendations and develop and BBDR model and approach to inform development of an MCLG.
- Stakeholder's response will generally be critical of the highly technical, underlying science to model perchlorate in sensitive lifestages and application of the model output to inform derivation of a perchlorate MCLG.
  - Industry groups (Perchlorate Study Group, American Chemistry Council); drinking water utilities, the U.S. Chamber of Commerce and the Department of Defense will likely be critical of the underlying science and that the peer review process was expedited.
  - Environmental groups will likely be critical of the underlying science.
  - Consumers, both those using public water systems and private wells, will be concerned about potential health risks from perchlorate.

<u>Requesting Peer Review Input On Appropriateness of:</u>

- Selection of studies to set model parameters
- Selection of fT4 value to define hypothyroxinemia
- Selection of 5% increase in the proportion of individuals deemed hypothyroxinemic
- Selection of PDI/MDI as end point
- Selection of 1% change in Bayleys Scales of Infant Development (PDI/MDI) as threshold
- Selection of 100 ug/day iodine nutrition level

Message

From: Kirby, Kevin [Kirby.Kevin@epa.gov]
Sent: 2/1/2013 6:54:41 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Carroll, Gregory [Carroll.Gregory@epa.gov]; Lopez-Carbo, Maria [Lopez-Carbo.Maria@epa.gov]; Phil Oshida [Oshida.PhilLNDU@usepa.onmicrosoft.com]
Subject: Re: Fw: Details for meeting on Perchlorate, Feb. 1, 2013
Attachments: Perchlorate RFC Briefing for OMB 01-29-13.docx; OMB Meeting Agenda RFC12004.doc

Eric,

In anticipation of our meeting this afternoon with OMB, I took the liberty of framing an agenda that I wanted to run by you.
Based on feedback, I'll print a few copies to take over to our meeting at the WHCC at 3:30.

Thanks,
Kevin

OMB Meeting
Agenda RFC120...

Kevin J. Kirby,
Enterprise Data Architect
OEI Quality Staff
US EPA
(202) 566-1656

From: Eric Burneson/DC/USEPA/US
To: Kevin Kirby/DC/USEPA/US@EPA
Cc: Ann Johnson/DC/USEPA/US@EPA, Gregory Carroll/CI/USEPA/US@EPA, Phil Oshida/DC/USEPA/US@EPA, Maria Lopez-Carbo/DC/USEPA/US@EPA
Date: 01/30/2013 12:52 PM
Subject: Fw: Details for meeting on Perchlorate, Feb. 1, 2013

Kevin:

Attached is the briefing document we prepared for Friday's meeting.

Perchlorate RFC
Briefing for OMB ...

Also please note that Greg Carroll will be participating via teleconference (I assume there will be a phone in the Jackson room and will give him the following call in number) Also please add and we need to Ann Johnson from the Office of Policy to the list of participants (I am not certain if Ann will attend in person or participate via teleconference).

Eric G. Burneson
Chief, Targeting and Analysis Branch
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency

Tel: 202-564-5250
Fax: 202-564-3760

----- Forwarded by Eric Burneson/DC/USEPA/US on 01/30/2013 12:42 PM -----

From: Kevin Kirby/DC/USEPA/US

To: "Schwab, Margo" <Margo_Schwab@omb.eop.gov>
Cc: Eric Burneson/DC/USEPA/US@EPA
Date: 01/29/2013 03:20 PM
Subject: RE: Details for meeting on Perchlorate, Feb. 1, 2013

At this juncture, I have the following individuals that will be attending:
Peter Grevatt
Phil Oshida
Eric Burneson
Kevin Kirby

Kevin J. Kirby,
Enterprise Data Architect
OEI Quality Staff
US EPA
(202) 566-1656

From: "Schwab, Margo" <Margo_Schwab@omb.eop.gov>
To: Kevin Kirby/DC/USEPA/US@EPA
Date: 01/29/2013 11:13 AM
Subject: RE: Details for meeting on Perchlorate, Feb. 1, 2013

Jackson Room.
Just send me a list of names. I don't need ssns or dobs

From: Kirby.Kevin@epamail.epa.gov [mailto:Kirby.Kevin@epamail.epa.gov]
Sent: Tuesday, January 29, 2013 10:54 AM
To: Schwab, Margo
Subject: Details for meeting on Perchlorate, Feb. 1, 2013

Hi Margo,

I just wanted to get some details on the location for the meeting this Friday at the WHCC for the RFC on Perchlorate before I send out the invite to those folks on the EPA side that will be participating.

Could I get a room number please?

Thanks,

Kevin

Kevin J. Kirby,

Enterprise Data Architect

OEI Quality Staff

US EPA

(202) 566-1656

OFFICE OF ENVIRONMENTAL INFORMATION

U.S. Chamber of Commerce
Request for Correction (RFC) 12004
Briefing to OMB on EPA draft Response

Agenda
Friday, Feb. 1, 2013
3:30 – 4:30pm

Meeting Location: White House Conference Center, Jackson Room

Dial-in = 866 299-3188,
Access code = 202 566-1656#

1. Introductions

2. Brief Overview of RFC and the IQG Process – Kevin

3. High Level Framing of U.S. Chamber of Commerce /RFC 12004

4. Discussion of Draft Response by EPA Office of Water – Eric

5. Next Steps
    a. OEI to provide template for response (Oct. 19, 2012)
    b. Reach consensus on draft response (Nov. 16, 2012)
    c. Submit response to CIO for review and clearance (Nov. 30, 2012)
    d. Submit draft response to OMB for clearance (Jan. .2, 2013)
    e. Comments back to EPA from OMB
    f. Draft response cleared for release to requester
    g. Response to Chamber (90 business days) due date – **Feb. 21, 2013**

Overview of RFC Process Flow at EPA
[EMBED Visio.Drawing.11]

[EMBED Visio.Drawing.11]

OFFICE OF ENVIRONMENTAL INFORMATION

Information Quality Guidelines issues – Kevin
Notes on Chamber of Commerce RFC submittal

Key Points from Submitted RFC:

A. **"UCMR data does not comply with data quality guidelines because it was not collected by accepted methods."**

- "EPA's reliance on flawed, non-objective data sunders the factual foundation *of it's determination to regulate perchlorate."*

- *Reliance on data collected during the first Unregulated Contamination Monitoring Rule (UCMR 1).*
  - analyzed drinking water data for 3,865 public water systems (PWS)
  - data reviewed for time period 2001 and 2005

- *EPA found 160 of the PWSs reported at least 1 analytical detection at levels greater than or equal the method reporting level of 4 ug/L.*

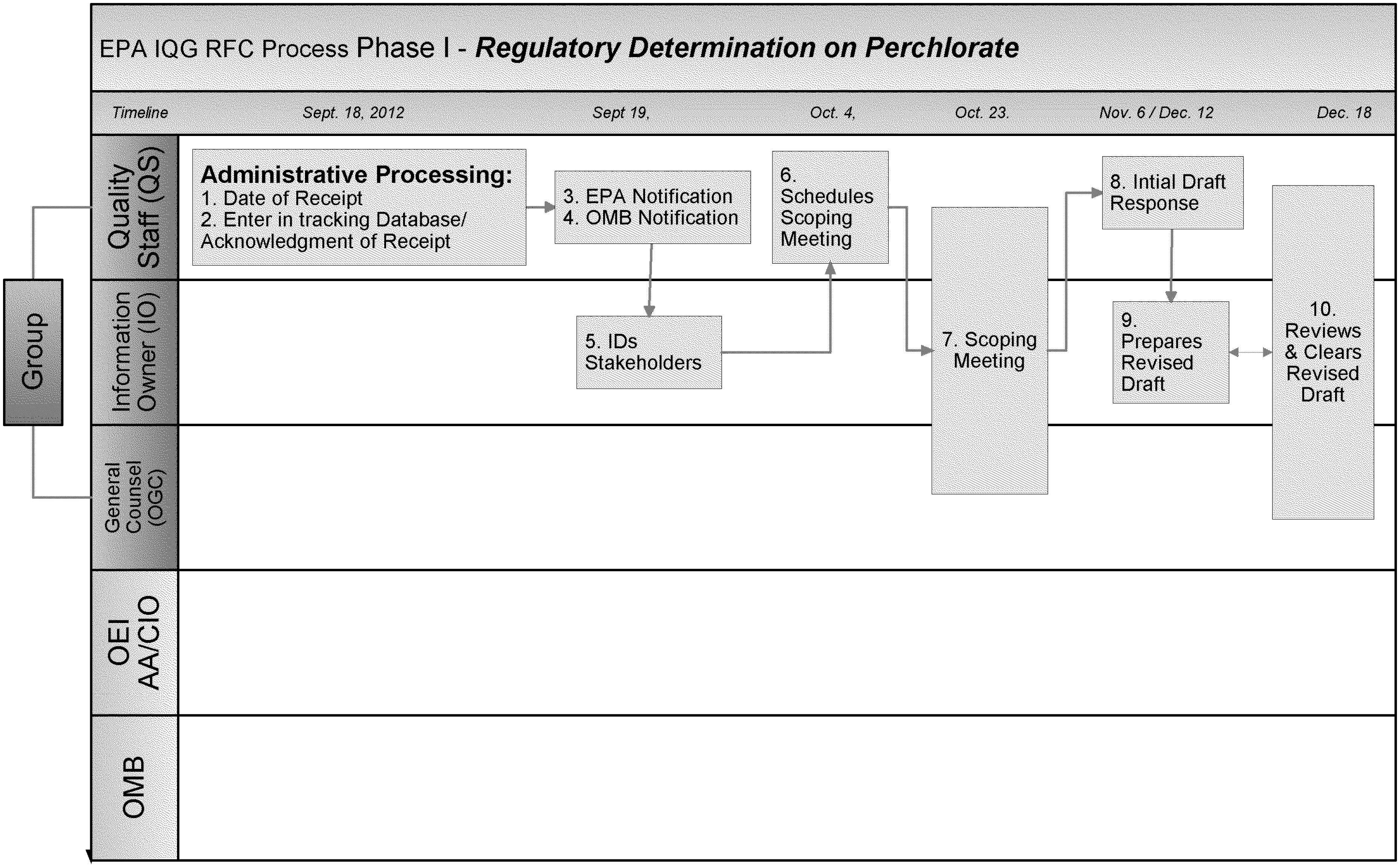
- According to petition, 31% of UCMR data is flawed because sample was not collected (documented) using acceptable methods. Specifically, sample location not correctly documented.
  - Sample location must be collected at "the point the water enters the distribution system – i.e.. ***after*** the water passed through any treatment or blending facilities."
  - "Instead, they were collected from untreated source water."

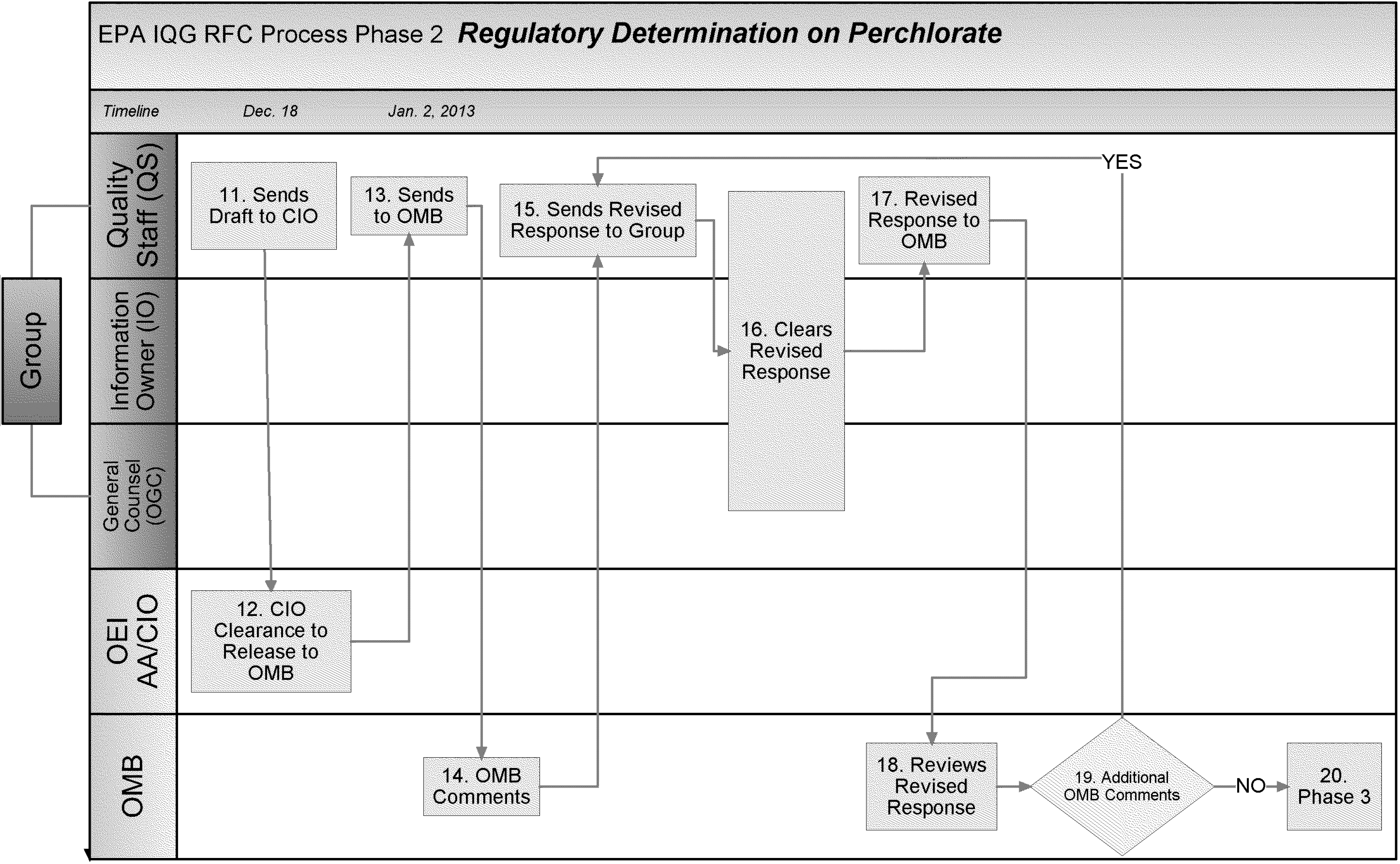
- Data used to develop UCMR was from Safe Drinking Water Accession and Review System (SDWARS)Safe Drinking Water Information System (SDWIS) database.

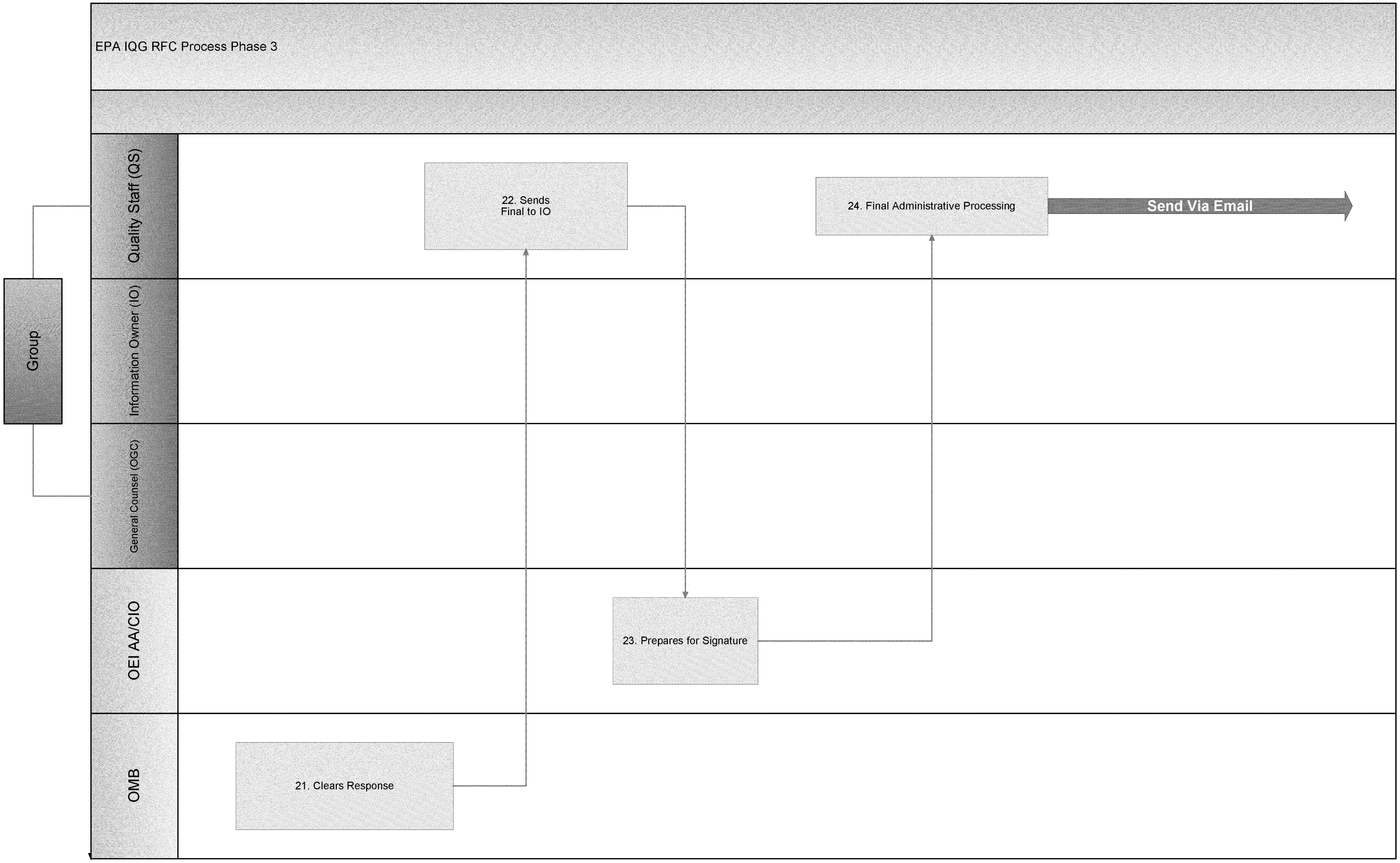
B. **"UCMR Data does not comply with data quality guidelines because it is not Representative of Current Conditions."**

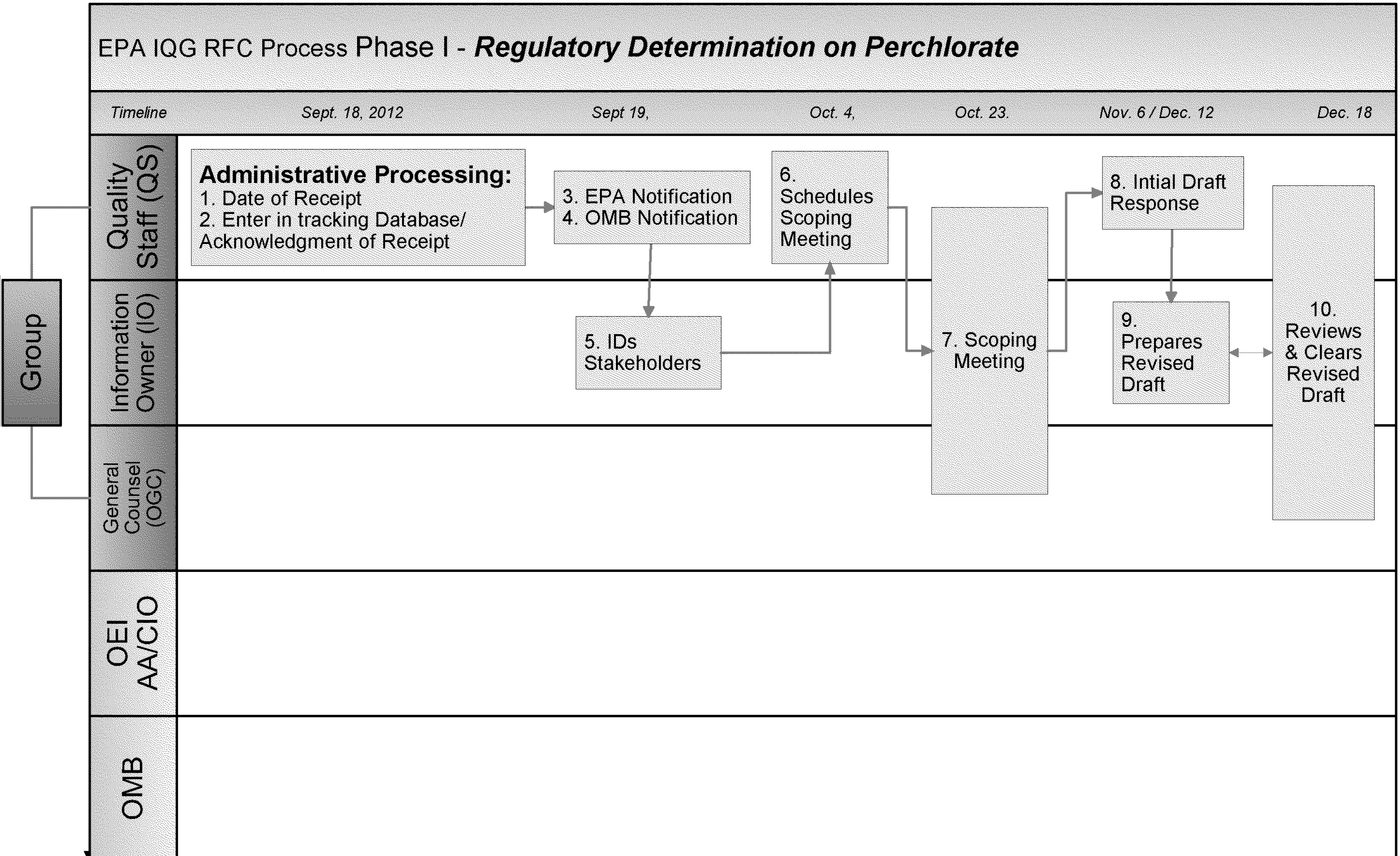
- **Several site specific studies were conducted, pointing to changes in infrastructure at selected Public Water Systems**

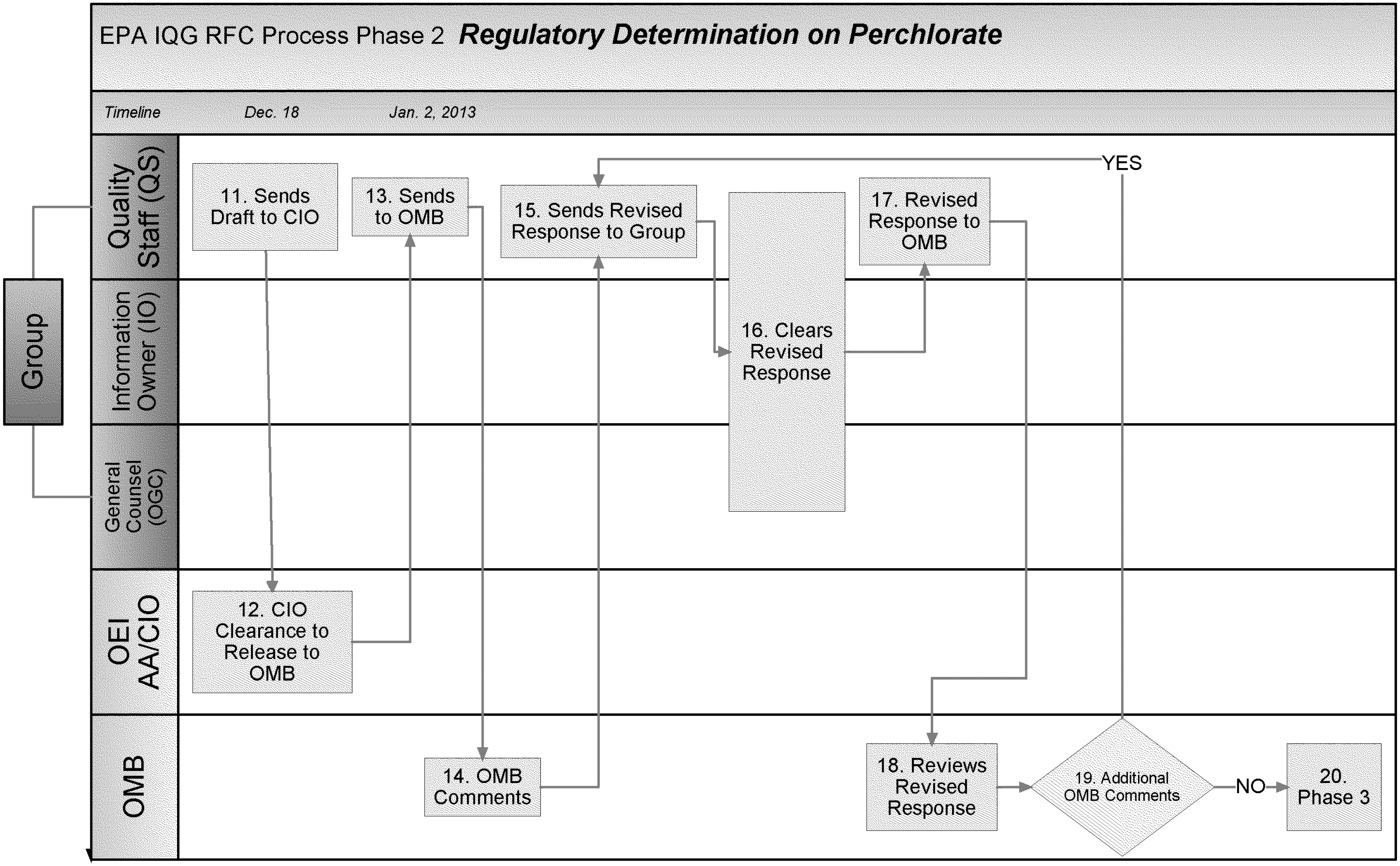
Draft and Deliberative
For EPA Internal Use




EPA IQG RFC Process Phase 2 Regulatory Determination on Perchlorate
Timeline
Dec. 18
Jan. 2, 2013
Group
Quality Staff (QS)
Information Owner (IO)
General Counsel (OGC)
OEI AA/CIO
OMB
11. Sends Draft to CIO
12. CIO Clearance to Release to OMB
13. Sends to OMB
14. OMB Comments
15. Sends Revised Response to Group
16. Clears Revised Response
17. Revised Response to OMB
18. Reviews Revised Response
19. Additional OMB Comments
YES
NO
20. Phase 3


EPA IQG RFC Process Phase 3
Group
Quality Staff (QS)
Information Owner (IO)
General Counsel (OGC)
OEI AA/CIO
OMB
21. Clears Response
22. Sends Final to IO
23. Prepares for Signature
24. Final Administrative Processing
Send Via Email


EPA IQG RFC Process Phase I - Regulatory Determination on Perchlorate
Timeline
Sept. 18, 2012
Sept 19,
Oct. 4,
Oct. 23.
Nov. 6 / Dec. 12
Dec. 18
Group
Quality Staff (QS)
Information Owner (IO)
General Counsel (OGC)
OEI AA/CIO
OMB
Administrative Processing:
1. Date of Receipt
2. Enter in tracking Database/ Acknowledgment of Receipt
3. EPA Notification
4. OMB Notification
5. IDs Stakeholders
6. Schedules Scoping Meeting
7. Scoping Meeting
8. Intial Draft Response
9. Prepares Revised Draft
10. Reviews & Clears Revised Draft



EPA IQG RFC Process Phase 2 Regulatory Determination on Perchlorate
Timeline
Dec. 18
Jan. 2, 2013
Group
Quality Staff (QS)
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11. Sends Draft to CIO
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16. Clears Revised Response
17. Revised Response to OMB
18. Reviews Revised Response
19. Additional OMB Comments
YES
NO
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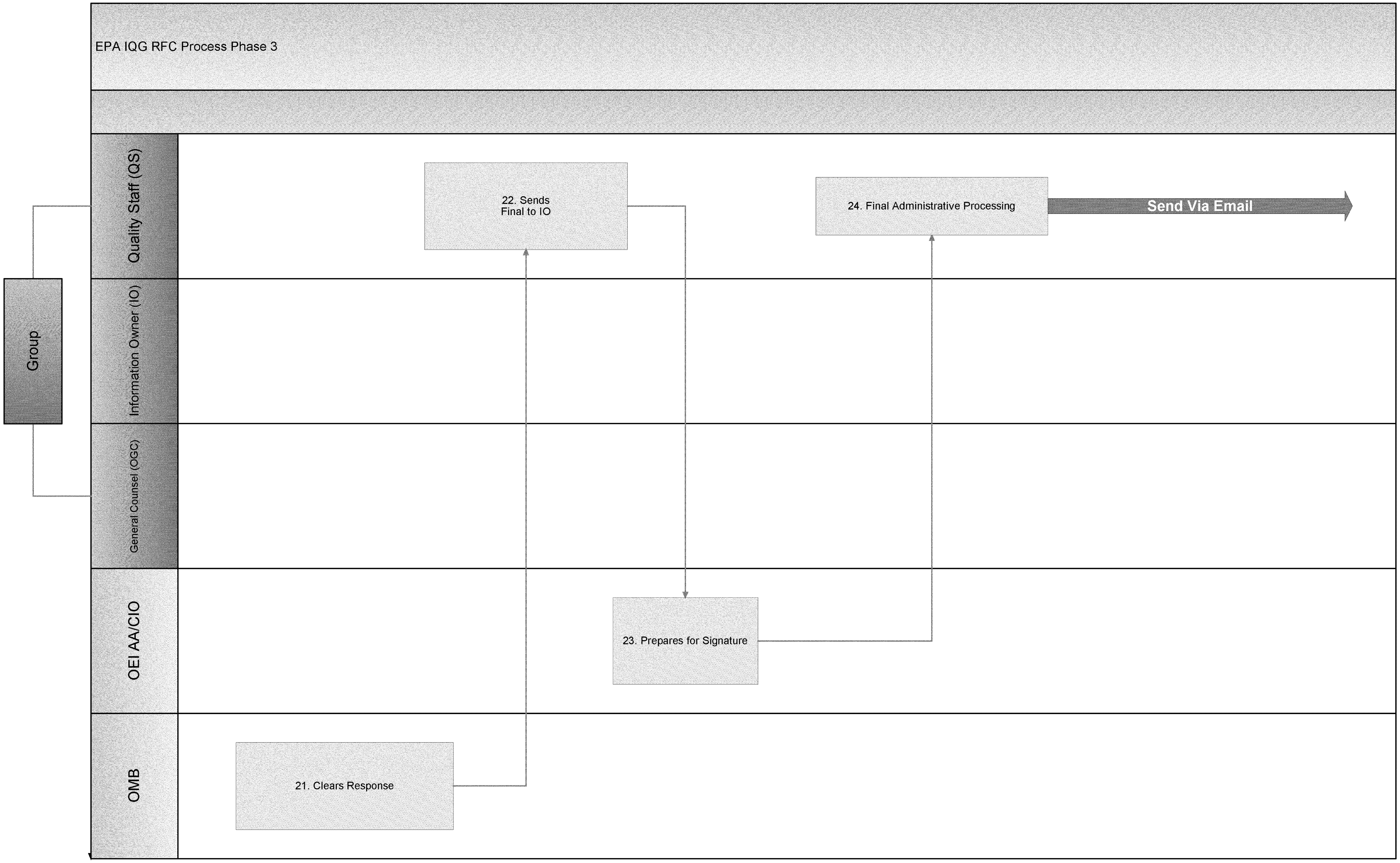

EPA IQG RFC Process Phase 3
Group
Quality Staff (QS)
Information Owner (IO)
General Counsel (OGC)
OEI AA/CIO
OMB
21. Clears Response
22. Sends Final to IO
23. Prepares for Signature
24. Final Administrative Processing
Send Via Email

Office of Management and Budget Briefing
Response to Perchlorate Request for Correction
2/1/2013

Purpose

- Provide OMB with an overview of the concerns expressed in comments provided by The U.S. Chamber of Commerce (The Chamber) and EPA's preliminary responses.

- Summarize and provide context on the significance of the included exhibits, as they relate to the Chamber's concerns.

Summary

- On February 2, 2011, EPA announced its decision to regulate perchlorate in drinking water,
    - EPA determined that perchlorate meets the Safe Drinking Water Act's (SDWA) three criteria for regulating a contaminant in drinking water. One of the three SDWA criteria is "The contaminant is known to occur or there is a substantial likelihood the contaminant will occur in public water systems (PWSs) with a frequency and at levels of public health concern. The data used to evaluate this criterion were collected under the first Unregulated Contaminant Monitoring Rule (UCMR 1). The UCMR 1 required 3,865 public water systems to monitor for perchlorate during the period of 2001 through 2005.
- On September 18, 2012, The Chamber submitted a request for correction (RFC) of the occurrence information from UCMR 1 that was developed and relied upon by the EPA to support its determination to regulate perchlorate under SDWA.
    - The Chamber indicated that EPA's determination to regulate perchlorate improperly relied upon flawed, non-objective occurrence data that do not meet the requirements as set forth in the Information Quality Act.
- The Chamber also stated that had EPA relied upon objective occurrence data available at the time of the regulatory determination, it is likely that EPA would not have been able to support the decision to regulate perchlorate. The Chamber's petition has two primary arguments for suggesting that the UCMR 1 data do not comply with the Information Quality Guidelines:

    1. The UCMR 1 data set EPA used in making its regulatory determination "was not collected by accepted methods, as described in the UCMR 1 regulations."

    2. The data EPA used in making its regulatory determination "are not representative of current conditions."

Chamber of Commerce Argument #1: EPA did not use acceptable data collection methods.

- The Chamber asserts that the UCMR 1 data (as cited in Exhibit A) are unreliable, as it was collected contrary to the methodology required by the UCMR 1 regulations.
    - This assertion is based on the belief that the accepted method of collecting occurrence data is to collect the sample at the point the water enters the distribution system (i.e., after the water has passed through any treatment or blending facilities).

EPA Response to Argument #1

- EPA acknowledges that a portion of the perchlorate UCMR 1 sample results are from source water samples. However, EPA disagrees with The Chamber, that the UCMR 1 data were not collected in accordance with accepted methods.
    - As EPA stated in the Federal Register on September 17, 1999, source water monitoring was explicitly allowed under the UCMR 1, under certain conditions: "...EPA modified the rule [from the proposal] to allow alternative sampling points to be used: sampling points identified by the State for compliance monitoring... and/or source (raw) water sampling points..."

Much of the data that The Chamber characterizes as unacceptable were, in fact, collected in accordance with this rule provision.

- Additionally, EPA believes the UCMR 1 satisfies the OMB guidelines as it is the best available nationally representative data set and the data were collected by accepted methods and/or best available methods.

Chamber of Commerce Argument #2: The data used in making the regulatory determination are not representative of current conditions.

- The Chamber also argues that more accurate and reliable data than UCMR 1 on perchlorate occurrence are now available and were available at the time of the regulatory determination, specifically data on public waster systems (PWSs) in California where a substantial number of UCMR 1 perchlorate detects occurred.

EPA Response to Argument #2

- EPA disagrees with the Chamber's assertion that more accurate and reliable data on perchlorate occurrence than the UCMR 1 data are available.
  - EPA evaluated available data on the frequency and level of perchlorate occurrence in PWSs including the California Department of Public Health (CDPH) data and concluded the UCMR 1 data are the best available, nationally representative, data on the frequency and level of perchlorate occurrence in PWSs.
    - EPA acknowledges that some levels of perchlorate may have decreased (due to remediation or actions by a PWS) since the samples were collected under UCMR 1.
    - However, in other cases the levels of perchlorate may have increased when perchlorate is introduced into a previously uncontaminated drinking water source or when a PWS commenced using a water source contaminated by perchlorate following UCMR 1 monitoring.
  - EPA does not believe it is appropriate to introduce bias into the analysis of national perchlorate occurrence by selectively eliminating only PWSs where there is information that suggests perchlorate levels have decreased.
  - Additionally, while The Chamber states that the monitoring data from the CDPH are a more recent, accurate, reliable, and complete data set, EPA evaluated CDPH monitoring data and found that the results were generally consistent with the UCMR 1 data.

Conclusion

- The EPA analysis referenced in the RFC was conducted by analyzing occurrence data for perchlorate from 3,865 PWSs and EPA believes the UCMR 1 data are the best available and the most extensive nationally representative data collected in accordance with accepted methods on the frequency and level of occurrence of perchlorate in drinking water.

- EPA provided two opportunities for public comment on the regulatory determination and considered those comments when making our final determination.

- EPA concludes that the scope and nature of our analysis conducted as part of the final regulatory determination were appropriate, and that the information presented in those analyses meets the standards of objectivity and utility.

- During the development of the proposed perchlorate rule, EPA will further evaluate the occurrence of perchlorate.

Office of Management and Budget Briefing
Response to Perchlorate Request for Correction
2/1/2013

APPENDIX
Summary of Exhibits Provided by The Chamber

Exhibit A: A Review of Perchlorate Occurrence in Public Drinking Water Systems

- A peer-reviewed journal article published in the Journal AWWA (Brandhuber et al, 2009), funded by the AWWA Water Industry Technical Action Fund.
- The study reviewed the results of the UCMR 1 and augmented those results with:
  - a telephone survey conducted by AWWA, and
  - several state perchlorate occurrence studies (AZ, CA, MA, and TX).
- Study concludes that less than 1% of all drinking water systems would be affected if an MCL of 20 ppb was established.
  - An MCL of 2 ppb would only affect 4% of the US PWSs.
- This exhibit is primarily cited to support Argument #1 by providing summary statistics on the number of UCMR 1 samples that were not taken at the entry point to the distribution system.

Exhibit B: Comments in Response to the Drinking Water: Perchlorate Supplemental Request for Comments [HQ-OW-2009-0297; FRL-8943-9].

- A copy of the Perchlorate Study Group Comments (prepared by Intertox) on EPA's 8/19/2009 FR notice asking for comment on alternate approaches to analyzing data related to EPA's perchlorate regulatory determination.
- These comments are included to support Argument #1 by providing some summary statistics on perchlorate occurrence in source water samples and entry point samples.
- This comment letter has been responded to as part of the Final Regulatory Determination for perchlorate.

Exhibit C: National Cost Implications of a Potential Perchlorate Regulation

- An AWWA report, prepared by Malcolm Pirnie, that estimates compliance costs for several potential MCLs (4, 6, 12, 18, and 24 ppb)
- Most perchlorate detections were between 4 and 12 ppb (based on UCMR 1 database).
  - Very few PWSs would be required to treat for perchlorate at the higher MCLs.
- A third of all perchlorate occurrences were in California.
- Costs associated with a 4 ppb MCL are approximately $140 million annually.
- These costs are to be borne by a small number of systems.
- A single treatment system was costed for this value: Single Pass Ion Exchange
- This reference is used to support Argument #2 as it contains summary statistics on the total number of perchlorate detections, as well as specific instances where perchlorate occurrences in the UCMR 1 dataset may no longer be present.

Exhibit D: Calculation Worksheet

- A worksheet used to support Argument #2, showing the calculations used by The Chamber to estimate the populations served by PWSs that had at least one detection above 6 ppb in California.

Exhibit E: California DPH Annual Compliance Report of Public Water Systems in 2009 and associated Appendices

- Report documenting CA compliance data from Jan 1, 2009 – Dec 31, 2009.
- Used to support Argument #2 by documenting the more recent drinking water data from CA and the number of public water systems that exceed California's MCL of 6 ppb. The Chamber also

used this to show the population associated with those systems in exceedance of the State MCL. This report is a summary of violations compiled by contaminant classes.

- Also includes three Appendices (3 of the 11 exhibits to the Chamber Of Commerce petition)
    - Appendix B is a breakdown of PWS violations by contaminant category
    - Appendix C is a listing of each PWS that reported a violation, and it includes the name of the PWS, the size of the affected population, and the number of MCL violations.
    - Appendix D is a listing of the violations by county.

Exhibit F: State Perchlorate Advisory Levels

- A list of State perchlorate advisory levels as of 4/20/05.
- Eight (8) states have advisory levels, ranging from 1 ppb to 51 ppb
- Used to support Argument #2 by listing perchlorate action levels implemented by states.

Exhibit G: State of Nevada Perchlorate Cleanup Projects

- A summary of NV activities to remediate perchlorate sites to reduce levels of perchlorate in the Lower Colorado River, dated 8/16/2011.
    - Contamination was traced to the Las Vegas Wash, a tributary of the Lower Colorado River.
- Perchlorate entering Las Vegas Wash has been reduced by 90% since 1997 through remediation at two sites.
- Includes the manner by which the two sites are remediating their groundwater.
- This was used to support Argument #2 by demonstrating actions taken by states to reduce perchlorate levels in drinking water.

Exhibit H: Water Quality Report City of Henderson, NV 2008

- City of Henderson, NV water quality report with water quality data from 2007
- Used to support Argument # 2 that UCMR 1 levels in Henderson, NV have decreased from 20 ppb during UCMR 1 to 5.9 ppb or below

Message

From: Damico, Brian [Damico.Brian@epa.gov]
Sent: 1/30/2013 5:23:39 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Re: Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt
Attachments: Perchlorate RFC Briefing for OMB 01-29-13.docx

Here it is. I'll drop the folder w/ the attachments off to you later today.

Perchlorate RFC
Briefing for OMB ...

Brian D'Amico
Chemical Engineer
Office of Water
United States Environmental Protection Agency
Mailcode 4607M
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
(202) 566-1069

From: Eric Burneson/DC/USEPA/US

To: Brian Damico/DC/USEPA/US@EPA
Date: 01/30/2013 12:19 PM
Subject: Re: Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt

Please Send me the updated version so I can distribute to participants.

From: Brian Damico/DC/USEPA/US

To: Gregory Carroll/CI/USEPA/US@EPA
Cc: Derek Losh/CI/USEPA/US@EPA, Eric Burneson/DC/USEPA/US@EPA
Date: 01/29/2013 10:08 AM
Subject: Re: Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt

Thanks,

Those will be incorporated in the OMB version!

Brian D'Amico
Chemical Engineer
Office of Water
United States Environmental Protection Agency
Mailcode 4607M
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
(202) 566-1069

From:	Gregory Carroll/CI/USEPA/US
To:	Brian Damico/DC/USEPA/US@EPA
Cc:	Derek Losh/CI/USEPA/US@EPA, Eric Burneson/DC/USEPA/US@EPA
Date:	01/29/2013 10:01 AM
Subject:	Re: Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt

Brian:

In re-reading the materials for this morning's meeting with Peter, I flagged a number of minor points. I realize that it's likely not practical to substitute a revised version for the 11am meeting, but I point these out as changes that should be considered for the materials that are sent to OMB.

One of the edits addresses a stray word introduced by my earlier edits. The other edits address the plural nature of the word "data." (In one of TSC's briefings with Peter, he pointed the latter out as a grammar issue he looks for.)

Thanks.

Greg

[attachment "Perchlorate RFC Briefing for PG 01-28-13_GJC comments.docx" deleted by Brian Damico/DC/USEPA/US]

From:	Brian Damico/DC/USEPA/US
To:	Daniel Olson/DC/USEPA/US@EPA, Derek Losh/CI/USEPA/US@EPA, Eric Burneson/DC/USEPA/US@EPA, Gregory Carroll/CI/USEPA/US@EPA, Meredith Russell/DC/USEPA/US@EPA, Phil Oshida/DC/USEPA/US@EPA, Maria Lopez-Carbo/DC/USEPA/US@EPA
Date:	01/28/2013 03:22 PM
Subject:	Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt

Good afternoon,

Attached are the materials for the briefing on the Preliminary Response to the Perchlorate Request for Correction with Peter Grevatt, scheduled for 11:00 am tomorrow morning. These materials have been reviewed and approved by my Acting Division Director, Phil Oshida. If you have any questions please contact myself or my Branch Chief, Eric Burneson.

Thank you for your time.

[attachment "Perchlorate RFC Briefing for PG 01-28-13.docx" deleted by Gregory Carroll/CI/USEPA/US]

Brian D'Amico
Chemical Engineer
Office of Water
United States Environmental Protection Agency
Mailcode 4607M
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
(202) 566-1069

Office of Management and Budget Briefing
Response to Perchlorate Request for Correction
2/1/2013

Purpose

- Provide OMB with an overview of the concerns expressed in comments provided by The U.S. Chamber of Commerce (The Chamber) and EPA's preliminary responses.

- Summarize and provide context on the significance of the included exhibits, as they relate to the commenters primary concerns.

Summary

- On February 2, 2011, EPA announced its decision to regulate perchlorate in drinking water,
  - EPA determined that perchlorate meets the Safe Drinking Water Act's (SDWA) three criteria for regulating a contaminant in drinking water. One of the three SDWA criteria is "The contaminant is known to occur or there is a substantial likelihood the contaminant will occur in public water systems (PWSs) with a frequency and at levels of public health concern. The data used to evaluate this criterion were collected under the first Unregulated Contaminant Monitoring Rule (UCMR 1). The UCMR 1 required 3,865 public water systems to monitor for perchlorate during the period of 2001 through 2005.
- On September 18, 2012, The Chamber submitted a request for correction (RFC) of the occurrence information from UCMR 1 that was developed and relied upon by the EPA to support its determination to regulate perchlorate under SDWA.
  - The Chamber indicated that EPA's determination to regulate perchlorate improperly relied upon flawed, non-objective occurrence data that do not meet the requirements as set forth in the Information Quality Act.
- The Chamber also stated that had EPA relied upon objective occurrence data available at the time of the regulatory determination, it is likely that EPA would not have been able to support the decision to regulate perchlorate. The Chamber's petition has two primary arguments for suggesting that the UCMR 1 data do not comply with the Information Quality Guidelines:

  1. The UCMR 1 data set EPA used in making its regulatory determination "was not collected by accepted methods, as described in the UCMR 1 regulations."

  2. The data EPA used in making its regulatory determination "are not representative of current conditions."

Chamber of Commerce Argument #1: EPA did not use acceptable data collection methods.

- The Chamber asserts that the UCMR 1 data (as cited in Exhibit A) are unreliable, as it was collected contrary to the methodology required by the UCMR 1 regulations.
  - This assertion is based on the belief that the accepted method of collecting occurrence data is to collect the sample at the point the water enters the distribution system (i.e., after the water has passed through any treatment or blending facilities).

EPA Response to Argument #1

- EPA acknowledges that a portion of the perchlorate UCMR 1 sample results are from source water samples. However, EPA disagrees with The Chamber, that the UCMR 1 data were not collected in accordance with accepted methods.
  - As EPA stated in the Federal Register on September 17, 1999, source water monitoring was explicitly allowed under the UCMR 1, under certain conditions: "…EPA modified the rule [from the proposal] to allow alternative sampling points to be used: sampling points identified by the State for compliance monitoring… and/or source (raw) water sampling points…"

Much of the data that The Chamber characterizes as unacceptable were, in fact, collected in accordance with this rule provision.
    - Additionally, EPA believes the UCMR 1 satisfies the OMB guidelines as it is the best available nationally representative data set and the data were collected by accepted methods and/or best available methods.

Chamber of Commerce Argument #2: The data used in making the regulatory determination are not representative of current conditions.

- The Chamber also argues that more accurate and reliable data than UCMR 1 on perchlorate occurrence are now available and were available at the time of the regulatory determination, specifically data on public waster systems (PWSs) in California where a substantial number of UCMR 1 perchlorate detects occurred.

EPA Response to Argument #2

- EPA disagrees with the Chamber's assertion that more accurate and reliable data on perchlorate occurrence than the UCMR 1 data are available.
    - EPA evaluated available data on the frequency and level of perchlorate occurrence in PWSs including the California Department of Public Health (CDPH) data and concluded the UCMR 1 data are the best available, nationally representative, data on the frequency and level of perchlorate occurrence in PWSs.
        - EPA acknowledges that some levels of perchlorate may have decreased (due to remediation or actions by a PWS) since the samples were collected under UCMR 1.
        - However, in other cases the levels of perchlorate may have increased when perchlorate is introduced into a previously uncontaminated drinking water source or when a PWS commenced using a water source contaminated by perchlorate following UCMR 1 monitoring.
    - EPA does not believe it is appropriate to introduce bias into the analysis of national perchlorate occurrence by selectively eliminating only PWSs where there is information that suggests perchlorate levels have decreased.
    - Additionally, while The Chamber states that the monitoring data from the CDPH are a more recent, accurate, reliable, and complete data set, EPA evaluated CDPH monitoring data and found that the results were generally consistent with the UCMR 1 data.

Conclusion

- The EPA analysis referenced in the RFC was conducted by analyzing occurrence data for perchlorate from 3,865 PWSs and EPA believes the UCMR 1 data are the best available and the most extensive nationally representative data collected in accordance with accepted methods on the frequency and level of occurrence of perchlorate in drinking water.

- EPA provided two opportunities for public comment on the regulatory determination and considered those comments when making our final determination.

- EPA concludes that the scope and nature of our analysis conducted as part of the final regulatory determination were appropriate, and that the information presented in those analyses meets the standards of objectivity and utility.

- During the development of the proposed perchlorate rule, EPA will further evaluate the occurrence of perchlorate.

Office of Management and Budget Briefing
Response to Perchlorate Request for Correction
2/1/2013

APPENDIX

Summary of Exhibits Provided by The Chamber

Exhibit A: A Review of Perchlorate Occurrence in Public Drinking Water Systems

- A peer-reviewed journal article published in the Journal AWWA (Brandhuber et al, 2009), funded by the AWWA Water Industry Technical Action Fund.
- The study reviewed the results of the UCMR 1 and augmented those results with:
  - a telephone survey conducted by AWWA, and
  - several state perchlorate occurrence studies (AZ, CA, MA, and TX).
- Study concludes that less than 1% of all drinking water systems would be affected if an MCL of 20 ppb was established.
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- These comments are included to support Argument #1 by providing some summary statistics on perchlorate occurrence in source water samples and entry point samples.
- This comment letter has been responded to as part of the Final Regulatory Determination for perchlorate.

Exhibit C: National Cost Implications of a Potential Perchlorate Regulation

- An AWWA report, prepared by Malcolm Pirnie, that estimates compliance costs for several potential MCLs (4, 6, 12, 18, and 24 ppb)
- Most perchlorate detections were between 4 and 12 ppb (based on UCMR 1 database).
  - Very few PWSs would be required to treat for perchlorate at the higher MCLs.
- A third of all perchlorate occurrences were in California.
- Costs associated with a 4 ppb MCL are approximately $140 million annually.
- These costs are to be borne by a small number of systems.
- A single treatment system was costed for this value: Single Pass Ion Exchange
- This reference is used to support Argument #2 as it contains summary statistics on the total number of perchlorate detections, as well as specific instances where perchlorate occurrences in the UCMR 1 dataset may no longer be present.

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used this to show the population associated with those systems in exceedance of the State MCL. This report is a summary of violations compiled by contaminant classes.

- Also includes three Appendices (3 of the 11 exhibits to the Chamber Of Commerce petition)
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    - Appendix C is a listing of each PWS that reported a violation, and it includes the name of the PWS, the size of the affected population, and the number of MCL violations.
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- A list of State perchlorate advisory levels as of 4/20/05.
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    - Contamination was traced to the Las Vegas Wash, a tributary of the Lower Colorado River.
- Perchlorate entering Las Vegas Wash has been reduced by 90% since 1997 through remediation at two sites.
- Includes the manner by which the two sites are remediating their groundwater.
- This was used to support Argument #2 by demonstrating actions taken by states to reduce perchlorate levels in drinking water.

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- City of Henderson, NV water quality report with water quality data from 2007
- Used to support Argument # 2 that UCMR 1 levels in Henderson, NV have decreased from 20 ppb during UCMR 1 to 5.9 ppb or below

Message

From: Grevatt, Peter [Grevatt.Peter@epa.gov]
Sent: 7/15/2016 9:55:36 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Re: perchlorate

Thx.

Sent from my iPhone

On Jul 15, 2016, at 5:46 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

> Vlad and Margo are the listed invitees for the call.
>
> **From:** Grevatt, Peter
> **Sent:** Friday, July 15, 2016 5:41 PM
> **To:** Burneson, Eric <Burneson.Eric@epa.gov>
> **Subject:** Re: perchlorate
>
> Thx. I remember the letters. No surprise there. Do you recall who froM ORIA requested the briefing? Did this come from Vlad?
>
> Sent from my iPhone
>
> On Jul 15, 2016, at 5:39 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:
>
>> We don't know specifically. It came from OIRA when they saw the BNA article about the FRN requesting additional peer reviewers for a combined panel that will look at both the model and the model application. Note that we have received correspondence on this issue from both the American Chemistry Council and the Perchlorate Study Group who do not support the consolidated time frame.
>>
>> **From:** Grevatt, Peter
>> **Sent:** Friday, July 15, 2016 5:37 PM
>> **To:** Burneson, Eric <Burneson.Eric@epa.gov>
>> **Subject:** Re: perchlorate
>>
>> Thanks. Can you please remind me of the genesis of the OMB request? I know you gave me a heads up before, and sorry that this is escaping my recollection. Been doing remarkably well today, but I think jet lag is putting me in a bit of a fog!
>>
>> Sent from my iPhone
>>
>> On Jul 15, 2016, at 5:25 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:
>>
>>> Attached please find the document we plan to use as the basis of our discussion with OMB on Tuesday morning. The attached reflects input from OGC. We had originally planned on having participation from OST as well but they now have conflicts with the revised date.

Also please note that we are scheduled to brief you on Monday at 11:00 am regarding the perchlorate MCLG derivation approaches that we expect to be presented in the paper.

From: Grevatt, Peter
Sent: Friday, July 15, 2016 5:12 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Greene, Ashley <Greene.Ashley@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>; Osegueda, Carlos <osegueda.carlos@epa.gov>
Subject: Fwd: perchlorate

FYI. Please let me know what is happening with OMB and when you expect to have a doc that outlines the draft MCLG. Thanks.

Sent from my iPhone

Begin forwarded message:

> **From:** "Beauvais, Joel" <Beauvais.Joel@epa.gov>
> **Date:** July 15, 2016 at 4:51:38 PM EDT
> **To:** "Grevatt, Peter" <Grevatt.Peter@epa.gov>
> **Subject: perchlorate**
>
> Peter – Meant to follow up with you on this. I don't need to review the model documentation, but I do need to understand what will be in the peer-review product (especially as it relates to numbers entailed by application of the model), as well as the plan on timing for public release etc. I also heard folks are planning to brief on OMB on this next week, so I'd like to get a handle on what's going on there. Shall we find some time early next week to walk through all this?
>
> **************
> I reviewed the perchlorate BBDR model documentation on the plane last night that came in from Ogwdw, ost and NCEA for the peer review, and will be sending my folks a track changes version tomorrow. This is a highly technical document and I don't think there will be value in your reviewing, but let me know whether you want to take a look. We'll soon be ready to pull the trigger on the peer review. We'll want to do coms and congressional and stakeholder heads up on that and we'll work with Travis and OCIR on materials which we will share with you. Please let me know if you want me to share the model documentation with you as well.

<OMB Peer Review Mtg .docx>

Message

From: Carroll, Gregory [Carroll.Gregory@epa.gov]
Sent: 1/29/2013 3:01:07 PM
To: Damico, Brian [Damico.Brian@epa.gov]
CC: Losh, Derek [Losh.Derek@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Re: Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt
Attachments: Perchlorate RFC Briefing for PG 01-28-13_GJC comments.docx

Brian:

In re-reading the materials for this morning's meeting with Peter, I flagged a number of minor points. I realize that it's likely not practical to substitute a revised version for the 11am meeting, but I point these out as changes that should be considered for the materials that are sent to OMB.

One of the edits addresses a stray word introduced by my earlier edits. The other edits address the plural nature of the word "data." (In one of TSC's briefings with Peter, he pointed the latter out as a grammar issue he looks for.)

Thanks.

Greg

Perchlorate RFC Briefing for PG 0...

From: Brian Damico/DC/USEPA/US

To: Daniel Olson/DC/USEPA/US@EPA, Derek Losh/CI/USEPA/US@EPA, Eric Burneson/DC/USEPA/US@EPA, Gregory Carroll/CI/USEPA/US@EPA, Meredith Russell/DC/USEPA/US@EPA, Phil Oshida/DC/USEPA/US@EPA, Maria Lopez-Carbo/DC/USEPA/US@EPA
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Brian D'Amico

Chemical Engineer
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1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
(202) 566-1069

Preparation for Office of Management and Budget Briefing
Preliminary Response to Perchlorate Request for Correction

Purpose

- Prepare to provide OMB with an overview of the concerns expressed in comments provided by The U.S. Chamber of Commerce (The Chamber) and EPA's preliminary responses.

- Obtain your input on materials for OMB briefing and discuss meeting strategy.

Summary

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  - EPA determined that perchlorate meets the Safe Drinking Water Act's (SDWA) three criteria for regulating a contaminant in drinking water. One of the three SDWA criteria is "The contaminant is known to occur or there is a substantial likelihood the contaminant will occur in public water systems (PWSs) with a frequency and at levels of public health concern. The data used to evaluate this criterion were collected under the first Unregulated Contaminant Monitoring Rule (UCMR 1). The UCMR 1 required 3,865 public water systems to monitor for perchlorate during the period of 2001 through 2005.
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American Chemistry Council

CAL DOOLEY
PRESIDENT AND CEO

RECEIVED

2016 JUN 24 AM 10: 06

OFFICE OF THE EXECUTIVE SECRETARIAT

June 20, 2016

The Honorable Gina McCarthy
Administrator
US Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Dear Administrator McCarthy:

I am writing about ongoing activities by the Environmental Protection Agency (EPA) to develop a maximum contaminant level goal (MCLG) for perchlorate in drinking water. In a June 3, 2016 Federal Register notice[1], EPA announced an expanded scope to its March 1, 2016 request for nominations for a peer review panel for the draft Biologically Based Dose-Response (BBDR) model. According to the notice, EPA is combining that panel with one that would have separately addressed the application of the model to develop a perchlorate MCLG. ACC is concerned that a compressed review process could unduly compromise the use of the best available science and limit the robustness of the peer review process to address these distinct scientific issues sufficiently.

A. The BBDR model requires a thorough scientific review separate and independent from its application to develop and MCGL for perchlorate.

The BBDR model was recommended by the EPA Science Advisory Board (SAB) for use in developing a perchlorate MCLG. In public and written comments,[2] ACC fully endorsed the development and use of a relevant model as an improved tool to derive a scientifically credible MCLG. The model development dominated the regulatory process, leading to a multi-year delay of the process as outlined under the Safe Drinking Water Act. Rushing the review now that the model is ready for evaluation with respect to perchlorate would be incongruous with the deliberative development of this sophisticated scientific tool.

---

[1] "Request for Nominations for Peer Reviewers for EPA's Draft Biologically Based Dose-Response (BBDR) Model for Perchlorate, Draft Model Support Document and Draft Approach for Deriving a Maximum Contaminant Level Goal (MCLG) for Perchlorate in Drinking Water," Federal Register Notice by the Environmental Protection Agency, 81 Federal Register 107 (3 June 2016), pp. 35760-35761.

[2] ACC Oral Comments to the EPA's Science Advisory Board, Perchlorate Advisory Panel (July 2012); ACC Written Comments to the EPA's Science Advisory Board, Perchlorate Advisory Panel (July 2012); ACC Written Comments to the EPA's Science Advisory Board, Perchlorate Advisory Panel (Sept. 2012); ACC Oral Comments to the National Drinking Water Advisory Council on Perchlorate (Oct. 2012); ACC Written Comments to the EPA's Science Advisory Board, Perchlorate Advisory Panel (Nov. 2012).

B. EPA must ensure that its peer review process preserves the objectivity and scientific integrity of a rigorous review to thoroughly address the scientific issues.

The tasks of the two original peer-review panels were separate and distinct. One panel was to review the developed BBDR model and another panel was to review the approaches to applying the BBDR model in the development of a perchlorate MCLG. Any combined panel should contain all the necessary expertise needed for a thorough and thoughtful review of key issues relevant to both original panels and devote sufficient time to adequately address these issues. Additionally, the tasks of any combined panel should be undertaken sequentially and involve (1) reviewing the merits of the developed model first and then (2) reviewing the applicability of the model to the development of a perchlorate MCLG. These conditions must be met, at a minimum, if EPA is to ensure that the combined panels "achieve efficiency and transparency in evaluating the development and application of key scientific products for analyzing perchlorate in drinking water," as noted in the Agency's June 3, 2016 Federal Register notice.

C. EPA must ensure a robust peer review process that allows for public input at each step.

Due the importance of this review, and the complexity of answering two distinct sets of charge questions, we recommend that EPA ensure that the peer review is consistent with the EPA SAB FY 12 initiatives to enhance public involvement in advisory activities.[3] It is critical that EPA ensure that the charge questions are appropriate and not unduly narrow. There should be an opportunity for the public to comment on the draft charge before it is finalized, and also an opportunity for the peer review committee members to discuss and edit the charge, if changes are requested.

As with other peer review meetings, when discussing both the content of the charge and the responses to the charge questions, in addition to providing written comments to the peer review panel, there should be clear opportunities for the public to present oral comments to the review panel, including opportunities for clarifying public comments at the end of the review meetings. Finally, it would be helpful if the peer reviewers provided responses to the substantive public comments that it receives throughout the review process.

Sincerely,

Cal Dooley

Cal Dooley

cc: Joel Beauvais – EPA, Office of Water
Peter Grevatt – EPA, Office of Ground Water and Drinking Water
Avi Garbow – EPA, Office of General Counsel

---

[3] See: https://yosemite.epa.gov/sab/sabproduct.nsf/Web/PublicInvolvement?OpenDocument

American Chemistry Council

700 2nd Street, NE, Washington, DC 20002

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The Honorable Gina McCarthy
Administrator
US Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

20460-

Message

From: Wadlington, Christina [Wadlington.Christina@epa.gov]
Sent: 9/12/2016 2:47:40 PM
To: Olson, Daniel [Olson.Daniel@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
CC: Perkinson, Russ [Perkinson.Russ@epa.gov]; Oshida, Phil [Oshida.Phil@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]
Subject: RE: revised FRNs - yes version if we do sequential peer review
Attachments: Perchlorate Roll Out_9.13.16.docx

Updated as requested.
Request your review and comment.

Thank you.

Christina Wadlington
Communications Director
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
Tel: 202.566.1859
Email: wadlington.christina@epa.gov
Webpage: www.epa.gov/safewater

From: Burneson, Eric
Sent: Monday, September 12, 2016 10:33 AM
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Cc: Perkinson, Russ; Burneson, Eric; Olson, Daniel; Messier, Dawn; Wadlington, Christina
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Dawn Messier
U.S.E.P.A.

Office of General Counsel
Water Law Office
202-564-5517

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Sent: Thursday, September 08, 2016 3:25 PM
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Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Perkinson, Russ <Perkinson.Russ@epa.gov>
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Notice #1 requests comments on the model and accompanying report, and

Notice #2 requests comment on the interim list of peer review candidates and charge.

The notices were revised based on comments from Lisa, Russ and myself.

Thanks,

Dan

From: Christ, Lisa
Sent: Thursday, September 08, 2016 12:37 PM
To: Perkinson, Russ <Perkinson.Russ@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>
Subject: revised FRNs - yes version if we do sequential peer review

Message

From: Wadlington, Christina [Wadlington.Christina@epa.gov]
Sent: 9/12/2016 4:11:21 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Olson, Daniel [Olson.Daniel@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
CC: Perkinson, Russ [Perkinson.Russ@epa.gov]; Oshida, Phil [Oshida.Phil@epa.gov]
Subject: RE: revised FRNs - yes version if we do sequential peer review
Attachments: Perchlorate Roll Out_9.12.16_V3.docx

Provided is an updated version that combines both Eric and Dan's comments. Please let me know if you have other edits or comments.

Eric, note that I shortened your text in the desk statement (approach one) a bit. If this version works, please let me know if you prefer to send to Joel or want it to go via the Comms path.

Thank you!

Christina Wadlington
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I also was reviewing and revising the rollout. Apologies to all for the duplication in the attached with what Dan prepared.
Dan and Christina can you check to make certain that the issues Dan and I identified are addressed and send forward the revised?

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Sent: Monday, September 12, 2016 11:34 AM
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Christina,

I revised the roll out to reflect today's thinking on the peer review process, namely –

- 21 day comment period for peer review candidates + charge/45 day comment period for the model and report
- Deleting mention of the draft report describing application of the model to inform development of a perchlorate MCLG. This may occur after the review of the model and report

- Addressed Peter's comments on the FRNs stating that the peer review meeting will held "in late 2016"
- Take a close look at our response under the revised heading, "**Why did we combine the two separate peer review panel meetings into one, then revert back to a combined panel?"**

Thanks,

Dan

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Perchlorate Peer Review
Communications Plan

PRE-PUBLICATION RELEASE DATE: TBD

ACTION: The agency is undertaking an independent, external panel peer review and announces the release of several materials for public comment that relate to the development of a maximum contaminant level goal for perchlorate.

KEY MESSAGES

- Perchlorate can disrupt the normal function of the thyroid gland in both children and adults.
- Perchlorate is of particular concern to infant and fetal development.
- The agency is releasing peer review materials that relate to the development of the Maximum Contaminant Level Goal (MCLG) for perchlorate.
- Based on the recommendations made by the SAB, EPA and FDA developed a biologically-based dose response (BBDR) model that can be used to inform derivation of an MCLG. Previously, EPA used a reference-dose to establish EPA's interim health advisory level of 15 µg/L.
- The use of the BBDR model to inform an MCLG is precedent-setting, therefore EPA is conducting a transparent and rigorous expert peer review process.
- After the peer review is complete, EPA will take the next appropriate steps.

ANTICIPATED REACTION

There is likely to be considerable interest and response to EPA's release of peer review materials and the peer review process itself. Over the past several years stakeholders have provided extensive comments on publically reviewable perchlorate materials and notices, met with EPA senior officials, managers and staff and have wrote the Administrator numerous letters.

EPA was recently sued by NRDC for the Agency's failure to issue proposed and final regulatory actions for perchlorate in accordance with the timelines provided in SDWA. EPA is currently negotiating with the petitioner to establish an agreeable schedule for development of the proposed action.

Stakeholders and the press are aware that EPA has been working to implement SAB recommendations and develop a BBDR model and approach to inform development of an MCLG.

Stakeholders may be critical of the highly technical, underlying science to model perchlorate in sensitive life stages and the novel application of the model output to inform the derivation of a perchlorate MCLG.

- Industry groups (Perchlorate Study Group, American Chemistry Council); drinking water utilities, the U.S. Chamber of Commerce and the Department of Defense will likely be critical of the underlying science and that the peer review process was expedited
- Environmental groups will likely be critical of the underlying science
- Consumers, both those using public water systems and private wells, will be concerned about potential health risks from perchlorate
- Congressional interest – Senator Boxer

DESK STATEMENT/Water Headlines

EPA made a determination in 2011 to regulate perchlorate to better protect public health and strengthen the safety of America's drinking water. Perchlorate is both a naturally occurring and manufactured chemical used in rocket propellant, explosives, fireworks and road flares. Exposure to perchlorate can have adverse health effects and has been found in some public drinking water systems at levels of concern.

As part of developing a drinking water standard for perchlorate, EPA is asking a panel of peer reviewers for comment on materials related to development of the Maximum Contaminant Level Goal (MCLG). The MCLG is the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. This level is one of the considerations in developing the enforceable maximum contaminant level (MCL) for a regulated contaminant.

Approach One
The perchlorate peer review materials are available for public comment and include a draft list of external peer review candidates, draft charge questions, the draft biologically-based dose response (BBDR) model and accompanying report, and a draft report on methodologies for approaches to apply modeling outputs to the development of the MCLG.

EPA is seeking public comment on the draft list of peer review candidates and the draft charge questions no later than 21 days after publication in the Federal Register. EPA is seeking public comment on the draft BBDR model and accompanying report no later than 45 days after publication in the Federal Register.

EPA had previously announced that, to achieve efficiency, it was expanding the scope of the peer review to include review of a draft approach for application of the draft BBDR model, to inform the development of a perchlorate MCLG. EPA has reevaluated that approach in response to concerns that a simultaneous review would not allow the Agency to consider peer reviewer comments on the draft model prior to evaluating its application. Therefore, EPA will seek input on a second peer review of methods for applying the model in a future notice. Today's notice therefore seeks input only on the peer review of the model, not its application.

Approach Two
EPA is seeking public comment on peer review of two perchlorate related scientific analyses, 1) a draft biologically-based dose response (BBDR) model and, 2) a draft report on methodologies for approaches to apply modeling outputs to the development of the MCLG. EPA is also seeking public comment on a draft list of external peer review candidates and draft charge questions.

EPA is seeking public comment on the draft list of peer review candidates and the draft charge questions no later than 21 days after publication in the Federal Register. EPA is seeking public comment on the draft BBDR model and accompanying report no later than 45 days after publication in the Federal Register.

Both Approaches
EPA will consider public and peer reviewer comments as the agency finalizes the peer review materials. The peer review panel is expected meet late in 2016 in Washington, D.C. EPA will announce the meeting in the Federal Register at least 30 days in advance.

Perchlorate Peer Review
Communications Plan

The external peer review will inform the next steps the agency takes toward establishing a maximum contaminant level goal (MCLG) for perchlorate. Once the MCLG is determined, EPA can set an enforceable standard.

Additional Background – HOLD unless need this level of technical detail
In 2011 EPA announced its decision to regulate perchlorate under the Safe Drinking Water Act (SDWA). In accordance with SDWA, the Agency requested EPA's Science Advisory Board (SAB) to review how to consider available data in deriving a Maximum Contaminant Level Goal (MCLG) for use in developing a perchlorate National Primary Drinking Water Regulation. The MCLG is a non-enforceable goal defined under the SDWA as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The MCLG is one of the considerations in developing the enforceable maximum contaminant level (MCL) for a regulated contaminant. The SAB released its final report on May 29, 2013 and recommended that EPA "derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling."

As recommended by the SAB, the agency, with contributions from FDA scientists, developed a BBDR model to determine under what conditions of iodine nutrition and exposure to perchlorate, that infants and lactating mothers would experience hypothyroxinemia (changes in thyroid hormone levels). EPA also developed approaches for deriving a perchlorate MCLG by using relationships from published literature to connect the changes in thyroid levels, as predicted by the BBDR model, to the development of the neurological system in infants and lactating mothers.

COMMUNICATIONS MATERIALS

External:

- Webpage (link will appear on https://www.epa.gov/dwstandardsregulations/perchlorate) will include:
    - Pre-publication notice
    - Link to Draft BBDR model
    - BBDR model accompanying report
    - Draft report on the application of the model to inform the development of a perchlorate MCLG
    - Peer review charge questions
    - Q&A (See marked Q&A below)
- Q&A (Consumer and Peer Review)
- Fact Sheet (developed from marked Q&A below)

Internal:

- Communications Plan with Roll out schedule
- Notification List
- Q&A

RELEASE SCHEDULE
w/o September 19

- Federal Agency Briefing (OGWDW)

-3 days

- OGWDW notification to Regional Contacts
- OPA notification to Regional PADS

-1 days

- OGWDW notification to federal partners
  - HHS including ATSDR, NIEHS and FDA
  - NIEHS
  - DOD
  - NASA
- OPA calls to federal agencies' communications counterparts at HHS (ATSDR, FDA, NIEHS), DOD and NASA

Pre-Pub release day [tbd]

9:00 a.m	Begin head's up calls to stakeholder list below
10:00 a.m	Congressional heads up emails
12:00 p.m	Website goes live – Broader congressional notifications (emails with link to website)
1:00 p.m	Social media and stakeholder notification via email (Water Headlines listserv)

STAKEHOLDER NOTIFICATION

<u>OGWDW</u>:

- Michael Deane, Director, National Association of Water Companies
- Tracy Mehan, Government Affairs Director, American Water Works Association
- Mike Paque, Executive Director, Groundwater Protection Council
- Jim Taft, Executive Director, Association of State Drinking Water Administrators
- Lynn Thorp, National Campaigns Director, Clean Water Action
- Diane Van de Hei, Executive Director, Association of Metropolitan Water Agencies
- Sam Wade, Executive Director, National Rural Water Association
- Mae Wu, Natural Resources Defense Council

<u>OLEM (OSRTI)</u>:

- Association of State and Territorial Solid Waste Management Officials

EXTERNAL & INTERNAL QUESTIONS AND ANSWERS

EXTERNAL CONSUMER QUESTIONS- for Website and/or Fact Sheet

Where is perchlorate found? (website and fact sheet)

Perchlorate occurs naturally in arid states in the Southwest United States, in nitrate fertilizer deposits in Chile, and in potash ore in the United States and Canada. It also forms naturally in the atmosphere. Perchlorate can be manufactured and used as an industrial chemical and can be found in rocket propellant, explosives, fireworks and road flares. It has also been found in some public drinking water systems and in food.

Why is perchlorate in drinking water a health concern? (website and fact sheet)

Perchlorate can disrupt the normal function of the thyroid gland in both children and adults. In adults, the thyroid plays an important role in metabolism, making and storing hormones that help regulate the heart rate, blood pressure, body temperature, and the rate at which food is converted into energy. In fetuses and infants, thyroid hormones are critical for normal growth and development of the central nervous system. Perchlorate can interfere with the human body's ability to absorb iodine into the thyroid gland which is a critical element in the production of thyroid hormones.

How does perchlorate get into my drinking water? (website and fact sheet)
Perchlorate dissolves easily, is relatively stable and is mobile in water. While it has often been detected in water supplies in close proximity to sites where solid rocket fuel is manufactured or used, there are also locations in the United States lacking a clearly defined source.

Besides drinking water, how else can people be exposed to perchlorate? (website and fact sheet)
People are exposed to perchlorate primarily through eating contaminated food or drinking water. The Food and Drug Administration (FDA) Total Diet Study combines nationwide sampling and analysis of hundreds of food items along with national surveys of food intake to develop comprehensive dietary exposure estimates for a variety of demographic groups in the U.S. In the 2005-2006 survey the FDA found detectable levels of perchlorate in 74 percent of the foods sampled. The complete set of FDA perchlorate data can be found here: [HYPERLINK "http://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm077685.htm"]

How do I know if perchlorate is in my water? (website and fact sheet)
Contact your local water supplier to find out if perchlorate is in your drinking water and what steps your utility is taking to reduce your exposure If you don't know who your local water supplier is, the information should be included in your latest water bill.

Can perchlorate be boiled out of my water? (website and fact sheet)
No, perchlorate cannot be removed by heating or boiling water.

How does a utility reduce/remove perchlorate? (website and fact sheet)
A number of options are available to drinking water systems to lower concentrations of perchlorate in the drinking water supply. In some cases, drinking water systems may be able to reduce concentrations of perchlorate by closing contaminated wells or changing rates of blending of water sources.

Perchlorate can be removed using a number of advanced treatment technologies. Each technology has advantages and disadvantages depending on the level of perchlorate present in the source water, removal goals, other water quality parameters, competing treatment objectives, and treatment waste disposal options. Regenerable and single-pass ion exchange, reverse osmosis, and fixed- and fluidized-bed biological treatment can all remove perchlorate from drinking water sources.

These treatment technologies are used by some public water systems today and should be carefully designed and maintained to ensure that they are effective for treating perchlorate.

I get my tap water from a private well. How can I find out if perchlorate is in my water? (website and fact sheet)
If you are concerned about the possibility of perchlorate in your drinking water and you are served by a private well, EPA recommends testing your drinking water. Approved laboratories can analyze a sample of your water to determine whether perchlorate is present and at what concentrations. More

information about private wells can be found here: [HYPERLINK "http://www.epa.gov/privatewells" \h].

Why did EPA decide to regulate perchlorate? (website)
The Safe Drinking Water Act (SDWA) requires that once every five years, EPA issue a Contaminant Candidate List (CCL). The CCL is a list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations, but are known or anticipated to occur in public water systems. Perchlorate was a part of CCL1 (1998), CCL2 (2005) and CCL3 (2009). In addition, EPA issues an Unregulated Contaminant Monitoring Rule (UCMR) to identify up to 30 unregulated contaminants to be monitored by large public water systems (PWSs) and a subset of small PWSs across the U.S. The UCMR provides EPA and other interested parties with nationally representative data on the occurrence of particular contaminants in drinking water. This data set lets the Agency assess the number of people potentially being exposed and provides an estimate of the levels of that exposure. Perchlorate was included in UCMR 1 (2001- 2005).

After issuing a CCL, EPA must decide whether to regulate at least five or more contaminants on the list (called Regulatory Determination). A Regulatory Determination is a formal decision on whether (or not) EPA should initiate a rulemaking process to develop a regulation for a specific contaminant or group of contaminants. In 2011, EPA announced its decision to regulate perchlorate under the Safe Drinking Water Act (SDWA). Specifically, EPA determined that perchlorate meets SDWA's criteria for regulating a contaminant--that is, perchlorate may have an adverse effect on the health of persons; perchlorate is known to occur or there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern; and in the sole judgment of the Administrator, regulation of perchlorate in drinking water systems presents a meaningful opportunity for health risk reduction for person served by public water systems.

Why is it taking so long for EPA to regulate perchlorate? (website)
In 2011, as required by SDWA, EPA sought recommendations from its Science Advisory Board on how to derive a health based MCLG prior to proposing a perchlorate regulation. SAB recommend an approach to evaluating health effects for the MCLG different from the one on which EPA had based its decision to regulate perchlorate. The SAB recommended EPA undertake development of a model to predict thyroid hormone changes that result from exposure to perchlorate. Since 2013, FDA and EPA scientists have been developing a model consistent with SAB recommendations to determine under what conditions of iodine nutrition and perchlorate exposure across sensitive lifestages would experience low serum free and total thyroxine (hypothyroxinemia). Currently, EPA is undertaking an expert panel peer review of scientific products to recommended by the SAB. EPA expects to hold the peer review panel meeting in late 2016. After the peer review is complete, EPA will take the next appropriate steps in establishing a NPDWR.

Why can't EPA just come up with an enforceable MCL? Why create a non-enforceable MCLG first?
When developing a National Primary Drinking Water Regulation (NPDWR), EPA must establish a maximum contaminant level goal (MCLG). The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. Once the MCLG is determined, EPA sets an enforceable standard (in most cases, a maximum contaminant level or MCL) as close to the MCLG as feasible, taking cost into consideration. The MCL is the maximum level allowed of a contaminant in water which is delivered to

any user of a public water system. The peer review materials will assist EPA with establishing an MCLG so that the Agency can then identify an enforceable MCL.

The peer review materials will assist EPA with establishing an MCLG. However, if EPA determines that a NPDWR for perchlorate is required, EPA will also establish an enforceable MCL at the same time.

Has a safe level of exposure for perchlorate been established? (website)
EPA has not yet established a maximum contaminant level goal for perchlorate. The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. On February 11, 2011, EPA determined that perchlorate meets the Safe Drinking Water Act criteria for regulation as a contaminant. The Agency found that perchlorate may have an adverse effect on the health of persons and is known to occur in public drinking water systems with a frequency and at levels that present a public health concern. Since that time, EPA has been reviewing the best available scientific data on a range of issues related to perchlorate in drinking water including its occurrence, treatment technologies, analytical methods and the costs and benefits of potential standards.

There also have been state actions on perchlorate such as standards, guidelines and advisories. In 2006, Massachusetts adopted a drinking water standard for perchlorate of 2 μg/L, and in 2007, California promulgated a standard of 6 μg/L. Twelve other states have established non-enforceable guidance, action or advisory levels. Depending on the state, a particular level may require a public water system to notify the public, serve as a screening tool for further action, or guide clean-up actions.

Customers that are served by a public water system can contact their local water supplier and ask for information on perchlorate in their drinking water.

EXTERNAL PEER REVIEW Q&A:

Why is EPA conducting a peer review? (website)
EPA will ask peer reviewers to comment on products that the agency will use to derive a Maximum Contaminant Level Goal (MCLG) for perchlorate. The MCLG is a non-enforceable goal defined under the Safe Drinking Water Act (SDWA) as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The MCLG is one of the considerations in developing the enforceable maximum contaminant level (MCL) for a regulated contaminant.

EPA believes that peer review is an important component of the scientific process. The critical feedback, suggestions, and new ideas provided by the peer reviewers stimulate creative thought, strengthen the interpretation of the reviewed material, and confer credibility on the product. The peer review objective is to provide advice to EPA on steps that will yield a highly credible scientific product that is supported by the scientific community.

Where can I find the review products? (website)
All documents in the docket are listed on the [HYPERLINK "http://www.regulations.gov"] website under Docket ID Numbers EPA-HQ-OW-2016-0438 and EPA-HQ-OW-2016-0439.

Can I provide comments on the review products? (website)

Yes. The public will have an opportunity to review and comment on charge questions and the draft reports undergoing review. Additionally, we intend to allow for people to make brief statements during the peer review meeting. Also, any Safe Drinking Water Act regulation on perchlorate will be subject to public notice and comment.

When will EPA establish a national drinking water standard for perchlorate? (website and/or fact sheet)

EPA will consider public comments and peer reviewer comments submitted in accordance with the Federal Register notice when finalizing the peer review products. After the peer review is complete, EPA will take the next appropriate steps.

INTERNAL CONSUMER Q&As:

Have public drinking water systems been sampled for perchlorate?
Both California and Massachusetts have drinking water regulations in place for perchlorate and extensive drinking water samples have been collected in those states. EPA included perchlorate in the first unregulated contaminant monitoring rule and a robust national sampling effort was conducted through the implementation of that rule. The sampling results are available on EPA's website at https://www.epa.gov/dwucmr/first-unregulated-contaminant-monitoring-rule. Customers served by a public water system can contact their local water supplier and ask if they test for perchlorate. If you are concerned about the possibility of perchlorate in your drinking water and you are served by a private well, EPA recommends testing your drinking water. In addition, EPA recommends that residents reach out to their local public health department for more information. More information about private wells can be found here: [HYPERLINK "http://www.epa.gov/privatewells" \h].

Should I be worried about making infant formula with tap water? [refer to FDA]

Should I consider taking iodine dietary supplements if I am worried about perchlorate? [refer to FDA]

Can I buy a home treatment device to remove perchlorate?
If you are concerned about perchlorate in your drinking water, you may consider purchasing a home treatment device such as a filter. However, in order to make a well-informed and cost-effective decision, consider checking with your water system to learn about the amount of perchlorate in your water and identifying a device that has been independently certified to remove perchlorate.

[HYPERLINK "http://www.nsf.org/consumer-resources/what-is-nsf-certification/water-filters-treatment-certification/contaminant-reduction-claims-guide" \t "_blank"], the [HYPERLINK "https://www.wqa.org/" \t "_blank"], [HYPERLINK "http://ul.com/" \t "_blank"] and [HYPERLINK "http://www.csagroup.org/global/en/services/testing-and-certification" \t "_blank"] all certify home treatment products for removal of contaminants. The relevant perchlorate removal standard is [HYPERLINK "http://www.nsf.org/consumer-resources/health-and-safety-tips/water-quality-treatment-tips/standards-for-water-treatment-systems" \t "_blank"]. If you choose to use a home treatment device, it is very important to follow the manufacturer's operation and maintenance instructions carefully in order to make sure the device works properly.

Perchlorate Peer Review
Communications Plan

INTERNAL PEER REVIEW QUESTIONS

What products will be reviewed?
The agency, with contributions from Food and Drug Administration scientists, developed a model (also known as a Biologically Based Dose-Response model, or BBDR) to determine what concentrations of perchlorate affect the thyroid gland levels in infants and lactating mothers. Peer reviewers will be asked to comment on the Draft Biologically Based Dose-Response Model (BBDR), model code and draft model report entitled "Biologically Based Dose-Response Models for the Effect of Perchlorate on Thyroid Hormones in the Infant, Breast Feeding Mother, Pregnant Mother, and Fetus: Model Development, Revision, and Preliminary Dose-Response Analyses."

APROACH 2 ONLY
EPA also developed approaches for deriving a perchlorate MCLG by using relationships from published literature to connect the changes in thyroid hormones, as predicted by the BBDR model, to hypothyroxinemia (changes in thyroid gland levels) or development of the neurological system. Peer reviewers will be asked to comment on the draft report entitled "Peer Review Draft: Proposed Approach to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water."

Additionally, EPA is seeking comments on the peer review charge and the interim list of expert peer review panel candidates.

How long is the comment period?
EPA announced that it is seeking public comments on two separate sets of materials. The first set is the interim list of peer review candidates and the draft charge. People should send their comments to Versar, Inc. no later than 21 days after publication in the Federal Register.

A companion notice, published on the same date, requests comments on the model and the draft model report. People should send their comments to the docket no later than 45 days after publication in the Federal Register.

Will the review panelists see my comments?
EPA will provide panelists a summary of the public comments submitted on the draft products. Panelists will also be given access to public comments submitted during the draft document's public comment period.

When and where and will EPA hold the meeting?
The meeting is projected to occur late in 2016 (exact date to be determined). EPA will announce the meeting in the Federal Register at least 30 days in advance to provide the meeting date, location and registration information. EPA anticipates holding the two-day meeting in the Washington, DC metro area.

What will EPA do with the public comments and panel recommendations?
EPA will provide panelists a summary of the public comments submitted on the draft products. Panelists will also be given access to public comments submitted during the draft document's public comment period.

Perchlorate Peer Review
Communications Plan

The contractor will provide a peer review summary report to EPA containing the final comments and recommendations from the panel of peer reviewers. EPA will make the final peer review report available to the public.

EPA will consider any public comments and peer reviewer comments submitted in accordance with the Federal Register notice when finalizing the products.

How did the contractor select the reviewers?
The contractor considered and screened all candidates against the selection criteria described in the March 1, 2016, and June 3, 2016, Federal Register notices (81 FR 10617 and 81 FR 35760, respectively) which included being free of any conflict of interest and available to participate in-person in a two-day peer review meeting in the Washington, DC area, during the projected fall/winter 2016 timeframe (exact date to be determined).

Following the screening process, the contractor narrowed the list of potential reviewers to 19 candidates. EPA is now soliciting comments on the interim list of 19 candidates.

What happens next?
Once the public comments on the interim list of candidates have been reviewed and considered, the contractor will select the final list of peer reviewers.

What happens after the peer reviewers are selected?
Following the selection process, the EPA will charge the peer reviewers with evaluating and providing written comments on the draft products. Additionally, peer reviewers will be provided a summary of public comments and given access to public comments submitted during the draft document's public comment period.

INTERNAL POLICY & DATA QUESTIONS AND ANSWERS:

What does EPA's data on perchlorate show?
The UCMR 1 perchlorate dataset is the best available nationally representative data on perchlorate occurrence in public water systems. Analytical detections of perchlorate at or above the minimum reporting level (4 µg/L) were identified in about 4% (155 of 3,865) of these systems. EPA estimates that between 5.1 million to 16.6 million people served by the sampled systems could be exposed to perchlorate in drinking water.

Why doesn't EPA require a contaminant to be monitored under more than one UCMR cycle?
Through each UCMR cycle, EPA anticipates a sufficient set of national monitoring data will be collected to properly characterize the level and frequency of occurrence in drinking water. Generally speaking, particular contaminants are not included in multiple UCMR cycles. Any decisions regarding future compliance monitoring will depend on the outcome of EPA's regulatory determination process. In the meantime, it is possible that particular states will establish additional unregulated contaminant monitoring requirements or recommendations for specific contaminants. PWSs are responsible for being aware of and complying with any state requirements.

What is the status of the NRDC complaint? [Reviewed by OGC]

Perchlorate Peer Review
Communications Plan

NRDC filed a complaint in SDNY in February alleging failure to propose and finalize an MCLG and NPDWR for perchlorate as required by SDWA 1412(b)(1)(E). That section requires that, after EPA makes a determination to regulate a contaminant under SDWA, the Agency must propose such regulations within 24 months and finalize within 18 months (with opportunity for one 9—month extension).
EPA and NRDC are discussing how to proceed with the litigation.

APPROACH 2 ONLY

Why did we combine the two separate peer review panel meetings into one?
EPA originally planned to conduct two separate peer review panels, starting with peer review of the model followed by a peer review of the MCLG report, including time between to make any necessary adjustments to the model. However, on February 18, 2016, NRDC filed a complaint in the U.S. District Court for the Southern District of N.Y. alleging that EPA failed to perform a nondiscretionary duty under SDWA (Section 1449(a)(2)) to propose and finalize a NPDWR for perchlorate. NRDC seeks court-ordered proposal and final deadlines; we are currently in settlement discussions with them.

In the meantime, in order to take advantage of efficiencies and to foster communication between all panelists, EPA is conducting a combined peer review panel meeting.

APPROACH 2 ONLY

Will the peer review products present alternative MCLGs?
No, the documents will not present alternative MCLGs, they present methodologies for approaches to derive and MCLG. However some experts can be expected to predict the MCLGs that would result from using the methodologies that are described in the documents.

APPROACH 2 ONLY

Will the methodologies that will be presented to the peer reviewers result in MCLGs that are in the range of MCLs set by California (6 µg/L) and Massachusetts (2 µg/L)?
Yes, these methodologies could produce MCLGs consistent with these states enforceable standards. Additionally, 12 states have guidance levels: AZ, FL, IL, KS, MD, NV, NJ, NM, NY, OR, TX, VT. The drinking water levels range from 1 to 18 µg/L. These levels may trigger public notice, serve as a screening tool for further action or guide cleanup action.

APPROACH 2 ONLY

The use of the perchlorate model to inform the MCLG is precedent setting for the drinking water program.

> **How will this novel approach fit into the definition of an MCLG?**
> The MCLG is defined as the level at which no known or anticipated adverse effects on the health of persons occur and which allows an *adequate margin of safety*. It is a non-enforceable public health goal based on best available peer reviewed science. EPA will need to give consideration of the applicability of the approach to the definition of MCLG.
>
> **Since this is a novel approach, does EPA understand uncertainties and limitation?**
> Although EPA discusses uncertainties and limitations in the draft reports, because it is novel it brings with it new uncertainties and limitations that may not yet be fully understood.
>
> **How might this impact the program?**

Perchlorate Peer Review
Communications Plan

EPA believes that the perchlorate rulemaking effort is a unique action. Information on perchlorate toxicology is data rich and models existed prior to EPA undertaking the current effort. Model development and panel peer reviews for future drinking water regulations should be considered on a contaminant-by-contaminant basis.

What is our evaluation of perchlorate occurrence data?
Estimates of perchlorate occurrence in public water systems are key drivers for national costs and benefits. EPA's Unregulated Contaminant Monitoring Regulation 1 (UCMR 1) 2001-2005 is the best available nationally representative data.

- 4.1% of public water systems (155/3,865) reported at least 1 perchlorate detection ≥ 4 µg/L (the minimum reporting level)
- 5.1 M to 16.6 M people served by the sampled systems could be exposed to perchlorate from drinking water

However, commenters have pointed out limitations of UCMR 1 for estimating current occurrence. The minimum reporting level is 4 µg/L. Since UCMR 1 data has been collected 2 states have enacted perchlorate standards (CA & MA) and remediation activities or new sources of perchlorate may have impacted concentration levels in public water systems. The US Chamber of Commerce challenged the UCMR1 occurrence data under the EPA's Information Quality Guidelines in 2012. For more information: [HYPERLINK "https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration" \l "12004"]

Are there any cross-office implications of promulgating a drinking water regulation?
Yes, potentially. Consistent with CERCLA section 121 and the National Contingency Plan, a promulgated drinking water MCL for perchlorate may be considered as a potential ARAR ("applicable or relevant and appropriate requirement"), depending on site-specific circumstances. Once promulgated, an MCL normally would be used instead of a Drinking Water Health Advisory for CERCLA response selection and implementation purposes (e.g., establishing a preliminary remediation goal and cleanup level).

The OIG and others have recommended doing a cumulative health risk assessment for perchlorate, nitrate and other thyroid-disrupting chemicals. Shouldn't we have included these chemicals in the model and/or approach?
Doing a cumulative assessment of all of the thyroid-disrupting chemicals would lead to substantial delay in action for perchlorate. While EPA acknowledges that nitrate and thiocyanate have the same mode of action as perchlorate, and that the effects of multiple thyroid-disrupting chemicals can be additive, EPA does not believe there are sufficient scientific data currently available to assess and characterize the combined risk of these contaminants.

Is there an Environmental Justice/Equity component for the affected communities?
Each community faces unique challenges when addressing concerns related to environmental issues. Perchlorate in drinking water is related to localized sources of contamination often near where it is manufactured or used. Currently, if water sampling results confirm that drinking water contains perchlorate at concentrations greater than 15 µg/L, water systems should undertake additional sampling to assess the level, scope and localized source of contamination to inform next steps.

How will the RfD, or the interim health advisory, be used to inform the MCLG?

Perchlorate Peer Review
Communications Plan

Based on SAB recommendations, EPA does not intend to use the perchlorate RfD to inform derivation of an MCLG. The SAB stated that it, ". . . recognizes that this is a novel approach as compared to previous MCLG derivations that use the RfD and exposure factors. However, PBPK/PDIUI modeling provides a more rigorous tool to integrate the totality of information available on perchlorate, and this approach may better address different life stage susceptibilities to perchlorate than the default MCLG approach."

Does perchlorate have a health advisory level?

Yes, on January 8, 2009, EPA released an interim drinking water health advisory of 15 parts of perchlorate for every billion parts of water (parts per billion or ppb) also referred to as 15 µg/L. EPA continues to evaluate the health effects of perchlorate and we anticipate that this interim drinking water health advisory may be re-evaluated as part of EPA's regulatory development process. For more information on the Interim Drinking Water Health Advisory for perchlorate can be found here: [HYPERLINK "http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P1004X7Q.txt"]

Can a person drink tap water containing perchlorate at or below the level of the health advisory every day of their life and not expect adverse health effects from these chemicals?

No, the Interim Subchronic Drinking Water Health Advisory of 15 micrograms per liter (µg/L), issued in December 2008, was derived to be protective of pregnant women for effects that can last a lifetime. The perchlorate interim subchronic HA covers a period of more than 30 days, but less than a year.

Message

From: Olson, Daniel [Olson.Daniel@epa.gov]
Sent: 9/12/2016 3:33:42 PM
To: Wadlington, Christina [Wadlington.Christina@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
CC: Perkinson, Russ [Perkinson.Russ@epa.gov]; Oshida, Phil [Oshida.Phil@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]
Subject: RE: revised FRNs - yes version if we do sequential peer review
Attachments: Perchlorate Roll Out_9 12 16 dgo.docx

Christina,

I revised the roll out to reflect today's thinking on the peer review process, namely –

- 21 day comment period for peer review candidates + charge/45 day comment period for the model and report
- Deleting mention of the draft report describing application of the model to inform development of a perchlorate MCLG. This may occur after the review of the model and report
- Addressed Peter's comments on the FRNs stating that the peer review meeting will held "in late 2016"
- Take a close look at our response under the revised heading, "**Why did we combine the two separate peer review panel meetings into one, then revert back to a combined panel?"**

Thanks,

Dan

From: Wadlington, Christina
Sent: Monday, September 12, 2016 10:48 AM
To: Olson, Daniel <Olson.Daniel@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Cc: Perkinson, Russ <Perkinson.Russ@epa.gov>; Oshida, Phil <Oshida.Phil@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

Updated as requested.
Request your review and comment.

Thank you.

Christina Wadlington
Communications Director
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
Tel: 202.566.1859
Email: wadlington.christina@epa.gov
Webpage: www.epa.gov/safewater

From: Burneson, Eric
Sent: Monday, September 12, 2016 10:33 AM
To: Wadlington, Christina <Wadlington.Christina@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>
Cc: Perkinson, Russ <Perkinson.Russ@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>; Oshida, Phil

<Oshida.Phil@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

Thanks Christina; Please note that Joel has also asked that we schedule a Federal Agency briefing in the next few weeks so the release plan should be modified to indicate that we will brief them next week, and the release schedule should indicate that we will notify all the contacts and Federal partners within 24 hours of signature. Also please list HHS (which includes FDA, ATSDR and NIEHS) NASA and DOD among the Federal partners we will notify.

From: Wadlington, Christina
Sent: Monday, September 12, 2016 10:24 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>
Cc: Perkinson, Russ <Perkinson.Russ@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>; Oshida, Phil <Oshida.Phil@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

Eric,

This was the last roll out sent to Joel. I'll update it to reflect the sequential review.

Christina Wadlington
Communications Director
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
Tel: 202.566.1859
Email: wadlington.christina@epa.gov
Webpage: www.epa.gov/safewater

From: Burneson, Eric
Sent: Monday, September 12, 2016 10:18 AM
To: Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>
Cc: Perkinson, Russ <Perkinson.Russ@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>; Oshida, Phil <Oshida.Phil@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

I have spoken with Dawn Messier and we still do not have a response from NRDC.

Now that Joel is back in the office we should revise the notice for his signature and send an electronic copy to Ann Campbell for Joe's review while we continue to wait for the NRDC response. Russ, can you work with Stephanie to get a revised FRN announcement up to Ann?

Christina: Joel has also asked for the comms rollout plan. Do we have a version that reflects a sequential peer review to share with him?

Thanks and apologies for the need to constantly adapt to the changes in plans.

Eric

From: Flaharty, Stephanie
Sent: Friday, September 09, 2016 10:41 AM
To: Olson, Daniel <Olson.Daniel@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>
Cc: Perkinson, Russ <Perkinson.Russ@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

I've made some corrections to spacing in the paragraph Dawn edited. Side note: The paragraph seems very wordy now ... hard for the reader to follow.

From: Olson, Daniel
Sent: Friday, September 09, 2016 10:30 AM
To: Messier, Dawn <Messier.Dawn@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>
Cc: Perkinson, Russ <Perkinson.Russ@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

I'll have a look, thanks.

From: Messier, Dawn
Sent: Friday, September 09, 2016 10:27 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>
Cc: Perkinson, Russ <Perkinson.Russ@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>
Subject: Re: revised FRNs - yes version if we do sequential peer review

Lisa -- I had some suggested edits to the new paragraph describing our change in approach. The goal was to describe our new process a bit more clearly and to ensure that readers understand that in the second peer review we will be seeking input on an "approach" for using the model to derive an MCLG, not asking reviewers to apply the model themselves. Thanks. Dawn

Carrie -- This is just FYI

From: Christ, Lisa
Sent: Thursday, September 8, 2016 5:03 PM
To: Flaharty, Stephanie; Greene, Ashley; Harris, Adrienne
Cc: Perkinson, Russ; Burneson, Eric; Olson, Daniel; Messier, Dawn; Wadlington, Christina
Subject: RE: revised FRNs - yes version if we do sequential peer review

All,
The attached FRNs include edits from Eric and Dawn and are awaiting Stephanie and Peters' review. If NRDC agrees to allow more time we can proceed with the peer reviews conducted in sequence as indicated in the attached notices. If NRDC does not agree we will need to re-group on Monday.
Lisa

From: Burneson, Eric
Sent: Thursday, September 08, 2016 4:24 PM
To: Messier, Dawn <Messier.Dawn@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Perkinson, Russ <Perkinson.Russ@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

I think the notice must include an acknowledgement of the fact that we are changing plans again and switching back to a series review with a reason. I have inserted that in the attached notice. The other notice is good (I don't think we need explanation in both).

From: Messier, Dawn
Sent: Thursday, September 08, 2016 4:13 PM
To: Olson, Daniel <Olson.Daniel@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Perkinson, Russ <Perkinson.Russ@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

These look fine. (Did see a stray comma after "Versar, Inc." on page 3, after "Selection Process.")

Dawn Messier
U.S.E.P.A.
Office of General Counsel
Water Law Office
202-564-5517

From: Olson, Daniel
Sent: Thursday, September 08, 2016 3:25 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Perkinson, Russ <Perkinson.Russ@epa.gov>
Subject: FW: revised FRNs - yes version if we do sequential peer review

Eric, Dawn and Steph,

Please find attached for your review in track changes the revised perchlorate FRNs. We're sending this for your review should we get a green light to do a sequential peer review. As a reminder,

Notice #1 requests comments on the model and accompanying report, and
Notice #2 requests comment on the interim list of peer review candidates and charge.

The notices were revised based on comments from Lisa, Russ and myself.

Thanks,

Dan

From: Christ, Lisa
Sent: Thursday, September 08, 2016 12:37 PM
To: Perkinson, Russ <Perkinson.Russ@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>
Subject: revised FRNs - yes version if we do sequential peer review

Perchlorate Peer Review
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PRE-PUBLICATION RELEASE DATE: TBD

ACTION: The agency is undertaking an independent, external panel peer review and announces the release of several materials for public comment that relate to the development of a maximum contaminant level goal for perchlorate.

KEY MESSAGES

- Perchlorate can disrupt the normal function of the thyroid gland in both children and adults.
- Perchlorate is of particular concern to infant and fetal ~~nervous system~~ development.
- The agency is releasing peer review materials that relate to the development of the Maximum Contaminant Level Goal (MCLG) for perchlorate.
- Based on the recommendations made by the SAB, EPA and FDA developed a biologically-based dose response (BBDR) model that can be used to ~~derive~~inform derivation of an MCLG. Previously, EPA used a reference-dose to establish EPA's interim health advisory level of 15 µg/L.
- The use of the BBDR model to inform an MCLG is precedent-setting, therefore EPA is conducting a transparent and rigorous expert peer review process.
- After the peer review is complete, EPA will take the next appropriate steps.

ANTICIPATED REACTION

There is likely to be considerable interest and response to EPA's release of peer review materials and the peer review process itself. Over the past several years stakeholders have provided extensive comments on publically reviewable perchlorate materials and notices, met with EPA senior officials, managers and staff and have wrote the Administrator numerous letters.

EPA was recently sued by NRDC for the Agency's failure to issue proposed and final regulatory actions for perchlorate in accordance with the timelines provided in SDWA. EPA is currently negotiating with the petitioner to establish an agreeable schedule for development of the proposed action.

Stakeholders and the press are aware that EPA has been working to implement SAB recommendations and develop a BBDR model and approach to inform development of an MCLG.

Stakeholders may be critical of the highly technical, underlying science to model perchlorate in sensitive life stages and the novel application of the model output to inform the derivation of a perchlorate MCLG.

- Industry groups (Perchlorate Study Group, American Chemistry Council); drinking water utilities, the U.S. Chamber of Commerce and the Department of Defense will likely be critical of the underlying science and that the peer review process was expedited
- Environmental groups will likely be critical of the underlying science
- Consumers, both those using public water systems and private wells, will be concerned about potential health risks from perchlorate
- Congressional interest – Senator Boxer

DESK STATEMENT/Water Headlines

EPA made a determination in 2011 to regulate perchlorate to better protect public health and strengthen the safety of America's drinking water. Perchlorate is both a naturally occurring and

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Communications Plan

manufactured chemical used in rocket propellant, explosives, fireworks and road flares. Exposure to perchlorate can have adverse health effects and has been found in some public drinking water systems at levels of concern.

As part of developing a drinking water standard for perchlorate, EPA is asking a panel of peer reviewers for comment on materials related to development of the Maximum Contaminant Level Goal (MCLG). The MCLG is the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. This level is one of the considerations in developing the enforceable maximum contaminant level (MCL) for a regulated contaminant.

Approach One

The perchlorate peer review materials are available for public comment and include a draft list of external peer review candidates, draft charge questions, the draft biologically-based dose response (BBDR) model and accompanying report, and a draft report on methodologies for approaches to apply modeling outputs to the development of the MCLG.

EPA is seeking public comment on the draft list of peer review candidates and the draft charge questions no later than ~~30~~21 days after publication in the Federal Register. EPA is seeking public comment on the draft BBDR model and accompanying report~~, and the draft report on methodologies for approaches to apply modeling outputs to the development of the MCLG~~ no later than ~~60~~45 days after publication in the Federal Register.

Commented [CW1]: Can someone check the timing in yellow to make sure they are all correct?

Approach Two

EPA is publishing two Federal Register notices and is seeking public on two separate sets of materials. The first notice requests for public comment on a draft list of external peer review candidates and draft charge questions. The second notice seeks public comment on the draft biologically-based dose response (BBDR) model and accompanying report~~, and a draft report on methodologies for approaches to apply modeling outputs to the development of the MCLG~~.

EPA is seeking public comment on the draft list of peer review candidates and the draft charge questions no later than 21 days after publication in the Federal Register. EPA is seeking public comment on the draft BBDR model and accompanying report~~, and the draft report on methodologies for approaches to apply modeling outputs to the development of the MCLG~~ no later than 45 days after publication in the Federal Register.

Both Approaches

EPA will consider public and peer reviewer comments as the agency finalizes the peer review materials. The peer review panel is expected meet ~~in the fall of~~ late in 2016 in Washington, D.C. EPA will announce the meeting in the Federal Register at least 30 days in advance.

The external peer review will inform the next steps the agency takes toward establishing a maximum contaminant level goal (MCLG) for perchlorate. Once the MCLG is determined, EPA can set an enforceable standard.

Additional Background – HOLD unless need this level of technical detail

In 2011 EPA announced its decision to regulate perchlorate under the Safe Drinking Water Act (SDWA). In accordance with SDWA, the Agency requested EPA's Science Advisory Board (SAB) to review how to consider available data in deriving a Maximum Contaminant Level Goal (MCLG) for use in developing a perchlorate National Primary Drinking Water Regulation. The MCLG is a non-enforceable goal defined under the SDWA as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The MCLG is one of the considerations in developing the enforceable maximum contaminant level (MCL) for a regulated contaminant. The SAB released its final report on May 29, 2013 and recommended that EPA "derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling."

As recommended by the SAB, the agency, with contributions from FDA scientists, developed a BBDR model to determine under what conditions of iodine nutrition and exposure to perchlorate, that infants and lactating mothers would experience hypothyroxinemia (changes in thyroid hormone levels). EPA also developed approaches for deriving a perchlorate MCLG by using relationships from published literature to connect the changes in thyroid levels, as predicted by the BBDR model, to the development of the neurological system in infants and lactating mothers.

COMMUNICATIONS MATERIALS

External:

- Webpage (link will appear on https://www.epa.gov/dwstandardsregulations/perchlorate) will include:
    - Pre-publication notice
    - Link to Draft BBDR model
    - BBDR model accompanying report
    - Draft report on the application of the model to inform the development of a perchlorate MCLG
    - Peer review charge questions
    - Q&A (See marked Q&A below)
- Q&A (Consumer and Peer Review)
- Fact Sheet (developed from marked Q&A below)

Internal:

- Communications Plan with Roll out schedule
- Notification List
- Q&A

RELEASE SCHEDULE

w/o September 19

- Federal Agency Briefing (OGWDW)

-3 days

- OGWDW notification to Regional Contacts
- OPA notification to Regional PADS

-1 days

- OGWDW notification to federal partners
    - FDA
    - HHS, ATSDR
    - NIEHS

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- DOD
- NASA

- OPA calls to federal agencies' communications counterparts at FDA, HHS (ATSDR), NIEHS

Pre-Pub release day [tbd]

9:00 a.m	Begin head's up calls to stakeholder list below
10:00 a.m	Congressional heads up emails
12:00 p.m	Website goes live – Broader congressional notifications (emails with link to website)
1:00 p.m	Social media and stakeholder notification via email (Water Headlines listserv)

STAKEHOLDER NOTIFICATION

OGWDW:

- Michael Deane, Director, National Association of Water Companies
- Tracy Mehan, Government Affairs Director, American Water Works Association
- Mike Paque, Executive Director, Groundwater Protection Council
- Jim Taft, Executive Director, Association of State Drinking Water Administrators
- Lynn Thorp, National Campaigns Director, Clean Water Action
- Diane Van de Hei, Executive Director, Association of Metropolitan Water Agencies
- Sam Wade, Executive Director, National Rural Water Association
- Mae Wu, Natural Resources Defense Council

OLEM (OSRTI):

- Association of State and Territorial Solid Waste Management Officials

EXTERNAL & INTERNAL QUESTIONS AND ANSWERS

EXTERNAL CONSUMER QUESTIONS- for Website and/or Fact Sheet

Where is perchlorate found? (website and fact sheet)

Perchlorate occurs naturally in arid states in the Southwest United States, in nitrate fertilizer deposits in Chile, and in potash ore in the United States and Canada. It also forms naturally in the atmosphere. Perchlorate can be manufactured and used as an industrial chemical and can be found in rocket propellant, explosives, fireworks and road flares. It has also been found in some public drinking water systems and in food.

Why is perchlorate in drinking water a health concern? (website and fact sheet)

Perchlorate can disrupt the normal function of the thyroid gland in both children and adults. In adults, the thyroid plays an important role in metabolism, making and storing hormones that help regulate the heart rate, blood pressure, body temperature, and the rate at which food is converted into energy. In fetuses and infants, thyroid hormones are critical for normal growth and development of the central nervous system. Perchlorate can interfere with the human body's ability to absorb iodine into the thyroid gland which is a critical element in the production of thyroid hormones.

How does perchlorate get into my drinking water? (website and fact sheet)

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Perchlorate dissolves easily, is relatively stable and is mobile in water. While it has often been detected in water supplies in close proximity to sites where solid rocket fuel is manufactured or used, there are also locations in the United States lacking a clearly defined source.

Besides drinking water, how else can people be exposed to perchlorate? (website and fact sheet)
People are exposed to perchlorate primarily through eating contaminated food or drinking water. The Food and Drug Administration (FDA) Total Diet Study combines nationwide sampling and analysis of hundreds of food items along with national surveys of food intake to develop comprehensive dietary exposure estimates for a variety of demographic groups in the U.S. In the 2005-2006 survey the FDA found detectable levels of perchlorate in 74 percent of the foods sampled. The complete set of FDA perchlorate data can be found here: [HYPERLINK "http://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm077685.htm"]

How do I know if perchlorate is in my water? (website and fact sheet)
Contact your local water supplier to find out if perchlorate is in your drinking water and what steps your utility is taking to reduce your exposure If you don't know who your local water supplier is, the information should be included in your latest water bill.

Can perchlorate be boiled out of my water? (website and fact sheet)
No, perchlorate cannot be removed by heating or boiling water.

How does a utility reduce/remove perchlorate? (website and fact sheet)
A number of options are available to drinking water systems to lower concentrations of perchlorate in the drinking water supply. In some cases, drinking water systems may be able to reduce concentrations of perchlorate by closing contaminated wells or changing rates of blending of water sources.

Perchlorate can be removed using a number of advanced treatment technologies. Each technology has advantages and disadvantages depending on the level of perchlorate present in the source water, removal goals, other water quality parameters, competing treatment objectives, and treatment waste disposal options. Regenerable and single-pass ion exchange, reverse osmosis, and fixed- and fluidized-bed biological treatment can all remove perchlorate from drinking water sources.

These treatment technologies are used by some public water systems today and should be carefully designed and maintained to ensure that they are effective for treating perchlorate.

I get my tap water from a private well. How can I find out if perchlorate is in my water? (website and fact sheet)
If you are concerned about the possibility of perchlorate in your drinking water and you are served by a private well, EPA recommends testing your drinking water. Approved laboratories can analyze a sample of your water to determine whether perchlorate is present and at what concentrations. More information about private wells can be found here: [HYPERLINK "http://www.epa.gov/privatewells" \h].

Why did EPA decide to regulate perchlorate? (website)
The Safe Drinking Water Act (SDWA) requires that once every five years, EPA issue a Contaminant Candidate List (CCL). The CCL is a list of contaminants that are currently not subject to any proposed or

promulgated national primary drinking water regulations, but are known or anticipated to occur in public water systems. Perchlorate was a part of CCL1 (1998), CCL2 (2005) and CCL3 (2009). In addition, EPA issues an Unregulated Contaminant Monitoring Rule (UCMR) to identify up to 30 unregulated contaminants to be monitored by large public water systems (PWSs) and a subset of small PWSs across the U.S. The UCMR provides EPA and other interested parties with nationally representative data on the occurrence of particular contaminants in drinking water. This data set lets the Agency assess the number of people potentially being exposed and provides an estimate of the levels of that exposure. Perchlorate was included in UCMR 1 (2001- 2005).

After issuing a CCL, EPA must decide whether to regulate at least five or more contaminants on the list (called Regulatory Determination). A Regulatory Determination is a formal decision on whether (or not) EPA should initiate a rulemaking process to develop a regulation for a specific contaminant or group of contaminants. In 2011, EPA announced its decision to regulate perchlorate under the Safe Drinking Water Act (SDWA). Specifically, EPA determined that perchlorate meets SDWA's criteria for regulating a contaminant--that is, perchlorate may have an adverse effect on the health of persons; perchlorate is known to occur or there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern; and in the sole judgment of the Administrator, regulation of perchlorate in drinking water systems presents a meaningful opportunity for health risk reduction for person served by public water systems.

Why is it taking so long for EPA to regulate perchlorate? (website)
In 2011, as required by SDWA, EPA sought recommendations from its Science Advisory Board on how to derive a health based MCLG prior to proposing a perchlorate regulation. SAB recommend an approach to evaluating health effects for the MCLG different from the one on which EPA had based its decision to regulate perchlorate. The SAB recommended EPA undertake development of a model to predict thyroid hormone changes that result from exposure to perchlorate. Since 2013, FDA and EPA scientists have been developing a model consistent with SAB recommendations to determine under what conditions of iodine nutrition and perchlorate exposure across sensitive lifestages would experience low serum free and total thyroxine (hypothyroxinemia). Currently, EPA is undertaking an expert panel peer review of the draft model, the accompanying draft report~~, and a draft report describing application of the model to inform the development of a perchlorate MCLG~~. EPA expects to hold the peer review panel meeting in ~~November (tentative)~~ late 2016. After the peer review is complete, EPA will take the next appropriate steps in establishing a NPDWR.

Why can't EPA just come up with an enforceable MCL? Why create a non-enforceable MCLG first?
When developing a National Primary Drinking Water Regulation (NPDWR), EPA must establish a maximum contaminant level goal (MCLG). The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. Once the MCLG is determined, EPA sets an enforceable standard. In most cases, the standard is a maximum contaminant level (MCL). The MCL is the maximum level allowed of a contaminant in water which is delivered to any user of a public water system. The MCL is set as close to the MCLG as feasible. Taking cost into consideration, EPA must determine the feasible MCL.

The peer review materials will assist EPA with establishing an MCLG. However, if EPA determines that a NPDWR for perchlorate is required, EPA will also establish an enforceable MCL at the same time.

Has a safe level of exposure for perchlorate been established? (website)

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EPA has not yet established a maximum contaminant level goal for perchlorate. The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. On February 11, 2011, EPA determined that perchlorate meets the Safe Drinking Water Act criteria for regulation as a contaminant. The Agency found that perchlorate may have an adverse effect on the health of persons and is known to occur in public drinking water systems with a frequency and at levels that present a public health concern. Since that time, EPA has been reviewing the best available scientific data on a range of issues related to perchlorate in drinking water including its occurrence, treatment technologies, analytical methods and the costs and benefits of potential standards.

There also have been state actions on perchlorate such as standards, guidelines and advisories. In 2006, Massachusetts adopted a drinking water standard for perchlorate of 2 μg/L, and in 2007, California promulgated a standard of 6 μg/L. Twelve other states have established non-enforceable guidance, action or advisory levels. Depending on the state, a particular level may require a public water system to notify the public, serve as a screening tool for further action, or guide clean-up actions.

Customers that are served by a public water system can contact their local water supplier and ask for information on perchlorate in their drinking water.

EXTERNAL PEER REVIEW Q&A:

Why is EPA conducting a peer review? (website)
EPA will ask peer reviewers to comment on products that the agency will use to derive a Maximum Contaminant Level Goal (MCLG) for perchlorate. The MCLG is a non-enforceable goal defined under the Safe Drinking Water Act (SDWA) as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The MCLG is one of the considerations in developing the enforceable maximum contaminant level (MCL) for a regulated contaminant.

EPA believes that peer review is an important component of the scientific process. The critical feedback, suggestions, and new ideas provided by the peer reviewers stimulate creative thought, strengthen the interpretation of the reviewed material, and confer credibility on the product. The peer review objective is to provide advice to EPA on steps that will yield a highly credible scientific product that is supported by the scientific community.

Where can I find the review products? (website)
All documents in the docket are listed on the [HYPERLINK "http://www.regulations.gov"] website under Docket ID Numbers EPA-HQ-OW-2016-0438 and EPA-HQ-OW-2016-0439.

Can I provide comments on the review products? (website)
Yes. The public will have an opportunity to review and comment on charge questions, the biologically based dose-response model and draft model report~~and the draft report describing application of the model to inform development of a perchlorate MCLG~~.

Additionally, we intend to allow for people to make brief statements during the peer review meeting. Also, any Safe Drinking Water Act regulation on perchlorate will be subject to public notice and comment.

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When will EPA establish a national drinking water standard for perchlorate? (website and/or fact sheet)

EPA will consider public comments and peer reviewer comments submitted in accordance with the Federal Register notice when finalizing the peer review products. After the peer review is complete, EPA will take the next appropriate steps.

INTERNAL CONSUMER Q&As:

Have public drinking water systems been sampled for perchlorate?
Both California and Massachusetts have drinking water regulations in place for perchlorate and extensive drinking water samples have been collected in those states. EPA included perchlorate in the first unregulated contaminant monitoring rule and a robust national sampling effort was conducted through the implementation of that rule. The sampling results are available on EPA's website at https://www.epa.gov/dwucmr/first-unregulated-contaminant-monitoring-rule. Customers served by a public water system can contact their local water supplier and ask if they test for perchlorate. If you are concerned about the possibility of perchlorate in your drinking water and you are served by a private well, EPA recommends testing your drinking water. In addition, EPA recommends that residents reach out to their local public health department for more information. More information about private wells can be found here: [HYPERLINK "http://www.epa.gov/privatewells" \h].

Should I be worried about making infant formula with tap water? [refer to FDA]

Should I consider taking iodine dietary supplements if I am worried about perchlorate? [refer to FDA]

Can I buy a home treatment device to remove perchlorate?
If you are concerned about perchlorate in your drinking water, you may consider purchasing a home treatment device such as a filter. However, in order to make a well-informed and cost-effective decision, consider checking with your water system to learn about the amount of perchlorate in your water and identifying a device that has been independently certified to remove perchlorate.

[HYPERLINK "http://www.nsf.org/consumer-resources/what-is-nsf-certification/water-filters-treatment-certification/contaminant-reduction-claims-guide" \t "_blank"], the [HYPERLINK "https://www.wqa.org/" \t "_blank"], [HYPERLINK "http://ul.com/" \t "_blank"] and [HYPERLINK "http://www.csagroup.org/global/en/services/testing-and-certification" \t "_blank"] all certify home treatment products for removal of contaminants. The relevant perchlorate removal standard is [HYPERLINK "http://www.nsf.org/consumer-resources/health-and-safety-tips/water-quality-treatment-tips/standards-for-water-treatment-systems" \t "_blank"]. If you choose to use a home treatment device, it is very important to follow the manufacturer's operation and maintenance instructions carefully in order to make sure the device works properly.

INTERNAL PEER REVIEW QUESTIONS

What products will be reviewed?

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The agency, with contributions from Food and Drug Administration scientists, developed a model (also known as a Biologically Based Dose-Response model, or BBDR) to determine what concentrations of perchlorate affect the thyroid gland levels in infants and lactating mothers. Peer reviewers will be asked to comment on the Draft Biologically Based Dose-Response Model (BBDR), model code and draft model report entitled "Biologically Based Dose-Response Models for the Effect of Perchlorate on Thyroid Hormones in the Infant, Breast Feeding Mother, Pregnant Mother, and Fetus: Model Development, Revision, and Preliminary Dose-Response Analyses."

~~EPA also developed approaches for deriving a perchlorate MCLG by using relationships from published literature to connect the changes in thyroid hormones, as predicted by the BBDR model, to hypothyroxinemia (changes in thyroid gland levels) or development of the neurological system. Peer reviewers will be asked to comment on the draft report entitled "Peer Review Draft: Proposed Approach to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water."~~

Additionally, EPA is seeking comments on the peer review charge and the interim list of expert peer review panel candidates.

How long is the comment period?
EPA announced that it is seeking public comments on two separate sets of materials. The first set is the interim list of peer review candidates and the draft charge. People should send their comments to Versar, Inc. no later than 21 days after publication in the Federal Register.

A companion notice, published on the same date, requests comments on the model~~,~~ and the draft model report ~~and the draft report on application of the model to inform derivation of a perchlorate MCLG~~. People should send their comments to the docket no later than 45 days after publication in the Federal Register.

Will the review panelists see my comments?
EPA will provide panelists a summary of the public comments submitted on the draft products. Panelists will also be given access to public comments submitted during the draft document's public comment period.

When and where and will EPA hold the meeting?
The meeting is projected to occur ~~during the fall of~~ late in 2016 (exact date to be determined). EPA will announce the meeting in the Federal Register at least 30 days in advance to provide the meeting date, location and registration information. EPA anticipates holding the two-day meeting in the Washington, DC metro area.

What will EPA do with the public comments and panel recommendations?
EPA will provide panelists a summary of the public comments submitted on the draft products. Panelists will also be given access to public comments submitted during the draft document's public comment period.

The contractor will provide a peer review summary report to EPA containing the final comments and recommendations from the panel of peer reviewers. EPA will make the final peer review report available to the public.

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EPA will consider any public comments and peer reviewer comments submitted in accordance with the Federal Register notice when finalizing the products.

How did the contractor select the reviewers?
The contractor considered and screened all candidates against the selection criteria described in the March 1, 2016, and June 3, 2016, Federal Register notices (81 FR 10617 and 81 FR 35760, respectively) which included being free of any conflict of interest and available to participate in-person in a two-day peer review meeting in the Washington, DC area, during the projected fall/winter 2016 timeframe (exact date to be determined).

Following the screening process, the contractor narrowed the list of potential reviewers to 19 candidates. EPA is now soliciting comments on the interim list of 19 candidates.

What happens next?
Once the public comments on the interim list of candidates have been reviewed and considered, the contractor will select the final list of peer reviewers.

What happens after the peer reviewers are selected?
Following the selection process, the EPA will charge the peer reviewers with evaluating and providing written comments on the draft products. Additionally, peer reviewers will be provided a summary of public comments and given access to public comments submitted during the draft document's public comment period.

INTERNAL POLICY & DATA QUESTIONS AND ANSWERS:

What does EPA's data on perchlorate show?
The UCMR 1 perchlorate dataset is the best available nationally representative data on perchlorate occurrence in public water systems. Analytical detections of perchlorate at or above the minimum reporting level (4 μg/L) were identified in about 4% (155 of 3,865) of these systems. EPA estimates that between 5.1 million to 16.6 million people served by the sampled systems could be exposed to perchlorate in drinking water.

Why doesn't EPA require a contaminant to be monitored under more than one UCMR cycle?
Through each UCMR cycle, EPA anticipates a sufficient set of national monitoring data will be collected to properly characterize the level and frequency of occurrence in drinking water. Generally speaking, particular contaminants are not included in multiple UCMR cycles. Any decisions regarding future compliance monitoring will depend on the outcome of EPA's regulatory determination process. In the meantime, it is possible that particular states will establish additional unregulated contaminant monitoring requirements or recommendations for specific contaminants. PWSs are responsible for being aware of and complying with any state requirements.

Why did we combine the two separate peer review panel meetings into one, then revert back to a combined panel**?**
~~EPA originally planned to conduct two separate peer review panels, starting with peer review of the model followed by a peer review of the MCLG report, including time between to make any necessary adjustments to the model. However, on February 18, 2016, NRDC filed a complaint in the U.S. District~~

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~~Court for the Southern District of N.Y. alleging that EPA failed to perform a nondiscretionary duty under SDWA (Section 1449(a)(2)) to propose and finalize a NPDWR for perchlorate. NRDC seeks court-ordered proposal and final deadlines; we are currently in settlement discussions with them.~~On June 3, 2016, the Agency announced in the Federal Register (81 FR 35760) that, to achieve efficiency, it was expanding the scope of the peer review announced in March to include review of a draft approach for application of the draft BBDR model, to inform the development of a perchlorate MCLG. EPA has reevaluated that approach in response to concerns that a simultaneous review of a methodology to applying the model to develop a perchlorate MCLG would not allow the Agency or peer reviews to consider peer reviewer comments on the draft BBDR model prior to evaluating the alternative methodologies to applying the model to derive an MCLG. Today's notice therefore seeks input only on the peer review of the model, not its application. EPA will seek input on a second peer review of methods for applying the model to inform development of a perchlorate MCLG in a future notice.

~~In the meantime, in order to take advantage of efficiencies and to foster communication between all panelists, EPA is conducting a combined peer review panel meeting.~~

What is the status of the NRDC complaint? [Reviewed by OGC]
NRDC filed a complaint in SDNY in February alleging failure to propose and finalize an MCLG and NPDWR for perchlorate as required by SDWA 1412(b)(1)(E). That section requires that, after EPA makes a determination to regulate a contaminant under SDWA, the Agency must propose such regulations within 24 months and finalize within 18 months (with opportunity for one 9—month extension).
EPA and NRDC are discussing how to proceed with the litigation.

Will the peer review products present alternative MCLGs?
No, the documents will not present alternative MCLGs, they present methodologies for approaches to derive and MCLG. However some experts can be expected to predict the MCLGs that would result from using the methodologies that are described in the documents.

Will the methodologies that will be presented to the peer reviewers result in MCLGs that are in the range of MCLs set by California (6 μg/L) and Massachusetts (2 μg/L)?
Yes, these methodologies could produce MCLGs consistent with these states enforceable standards. Additionally, 12 states have guidance levels: AZ, FL, IL, KS, MD, NV, NJ, NM, NY, OR, TX, VT. The drinking water levels range from 1 to 18 μg/L. These levels may trigger public notice, serve as a screening tool for further action or guide cleanup action.

The use of the perchlorate model to inform the MCLG is precedent setting for the drinking water program.

> **How will this novel approach fit into the definition of an MCLG?**
> The MCLG is defined as the level at which no known or anticipated adverse effects on the health of persons occur and which allows an *adequate margin of safety*. It is a non-enforceable public health goal based on best available peer reviewed science. EPA will need to give consideration of the applicability of the approach to the definition of MCLG.
>
> **Since this is a novel approach, does EPA understand uncertainties and limitation?**

Perchlorate Peer Review
Communications Plan

Although EPA discusses uncertainties and limitations in the draft reports, because it is novel it brings with it new uncertainties and limitations that may not yet be fully understood.

How might this impact the program?
EPA believes that the perchlorate rulemaking effort is a unique action. Information on perchlorate toxicology is data rich and models existed prior to EPA undertaking the current effort. Model development and panel peer reviews for future drinking water regulations should be considered on a contaminant-by-contaminant basis.

What is our evaluation of perchlorate occurrence data?
Estimates of perchlorate occurrence in public water systems are key drivers for national costs and benefits. EPA's Unregulated Contaminant Monitoring Regulation 1 (UCMR 1) 2001-2005 is the best available nationally representative data.

- 4.1% of public water systems (155/3,865) reported at least 1 perchlorate detection ≥ 4 μg/L (the minimum reporting level)
- 5.1 M to 16.6 M people served by the sampled systems could be exposed to perchlorate from drinking water

However, commenters have pointed out limitations of UCMR 1 for estimating current occurrence. The minimum reporting level is 4 μg/L. Since UCMR 1 data has been collected 2 states have enacted perchlorate standards (CA & MA) and remediation activities or new sources of perchlorate may have impacted concentration levels in public water systems. The US Chamber of Commerce challenged the UCMR1 occurrence data under the EPA's Information Quality Guidelines in 2012. For more information: [HYPERLINK "https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration" \l "12004"]

Are there any cross-office implications of promulgating a drinking water regulation?
Yes, potentially. Consistent with CERCLA section 121 and the National Contingency Plan, a promulgated drinking water MCL for perchlorate may be considered as a potential ARAR ("applicable or relevant and appropriate requirement"), depending on site-specific circumstances. Once promulgated, an MCL normally would be used instead of a Drinking Water Health Advisory for CERCLA response selection and implementation purposes (e.g., establishing a preliminary remediation goal and cleanup level).

The OIG and others have recommended doing a cumulative health risk assessment for perchlorate, nitrate and other thyroid-disrupting chemicals. Shouldn't we have included these chemicals in the model and/or approach?
Doing a cumulative assessment of all of the thyroid-disrupting chemicals would lead to substantial delay in action for perchlorate. While EPA acknowledges that nitrate and thiocyanate have the same mode of action as perchlorate, and that the effects of multiple thyroid-disrupting chemicals can be additive, EPA does not believe there are sufficient scientific data currently available to assess and characterize the combined risk of these contaminants.

Is there an Environmental Justice/Equity component for the affected communities?
Each community faces unique challenges when addressing concerns related to environmental issues. Perchlorate in drinking water is related to localized sources of contamination often near where it is manufactured or used. Currently, if water sampling results confirm that drinking water contains

perchlorate at concentrations greater than 15 µg/L, water systems should undertake additional sampling to assess the level, scope and localized source of contamination to inform next steps.

How will the RfD, or the interim health advisory, be used to inform the MCLG?
Based on SAB recommendations, EPA does not intend to use the perchlorate RfD to inform derivation of an MCLG. The SAB stated that it, ". . . recognizes that this is a novel approach as compared to previous MCLG derivations that use the RfD and exposure factors. However, PBPK/PDIUI modeling provides a more rigorous tool to integrate the totality of information available on perchlorate, and this approach may better address different life stage susceptibilities to perchlorate than the default MCLG approach."

Does perchlorate have a health advisory level?
Yes, on January 8, 2009, EPA released an interim drinking water health advisory of 15 parts of perchlorate for every billion parts of water (parts per billion or ppb) also referred to as 15 µg/L. EPA continues to evaluate the health effects of perchlorate and we anticipate that this interim drinking water health advisory may be re-evaluated as part of EPA's regulatory development process. For more information on the Interim Drinking Water Health Advisory for perchlorate can be found here: [HYPERLINK "http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P1004X7Q.txt"]

Can a person drink tap water containing perchlorate at or below the level of the health advisory every day of their life and not expect adverse health effects from these chemicals?
No, the Interim Subchronic Drinking Water Health Advisory of 15 micrograms per liter (µg/L), issued in December 2008, was derived to be protective of pregnant women for effects that can last a lifetime. The perchlorate interim subchronic HA covers a period of more than 30 days, but less than a year.

Message

From: Wadlington, Christina [Wadlington.Christina@epa.gov]
Sent: 9/12/2016 2:24:20 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Flaharty, Stephanie [Flaharty.Stephanie@epa.gov]; Olson, Daniel [Olson.Daniel@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Greene, Ashley [Greene.Ashley@epa.gov]; Harris, Adrienne [Harris.Adrienne@epa.gov]
CC: Perkinson, Russ [Perkinson.Russ@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Oshida, Phil [Oshida.Phil@epa.gov]
Subject: RE: revised FRNs - yes version if we do sequential peer review
Attachments: Perchlorate Roll Out_8 24 16.docx

Eric,

This was the last roll out sent to Joel. I'll update it to reflect the sequential review.

Christina Wadlington
Communications Director
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
Tel: 202.566.1859
Email: wadlington.christina@epa.gov
Webpage: www.epa.gov/safewater

From: Burneson, Eric
Sent: Monday, September 12, 2016 10:18 AM
To: Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>
Cc: Perkinson, Russ <Perkinson.Russ@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>; Oshida, Phil <Oshida.Phil@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

I have spoken with Dawn Messier and we still do not have a response from NRDC.

Now that Joel is back in the office we should revise the notice for his signature and send an electronic copy to Ann Campbell for Joe's review while we continue to wait for the NRDC response. Russ, can you work with Stephanie to get a revised FRN announcement up to Ann?

Christina: Joel has also asked for the comms rollout plan. Do we have a version that reflects a sequential peer review to share with him?

Thanks and apologies for the need to constantly adapt to the changes in plans.

Eric

From: Flaharty, Stephanie
Sent: Friday, September 09, 2016 10:41 AM
To: Olson, Daniel <Olson.Daniel@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>
Cc: Perkinson, Russ <Perkinson.Russ@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Wadlington, Christina

<Wadlington.Christina@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

I've made some corrections to spacing in the paragraph Dawn edited. Side note: The paragraph seems very wordy now … hard for the reader to follow.

From: Olson, Daniel
Sent: Friday, September 09, 2016 10:30 AM
To: Messier, Dawn <Messier.Dawn@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>
Cc: Perkinson, Russ <Perkinson.Russ@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

I'll have a look, thanks.

From: Messier, Dawn
Sent: Friday, September 09, 2016 10:27 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>
Cc: Perkinson, Russ <Perkinson.Russ@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>
Subject: Re: revised FRNs - yes version if we do sequential peer review

Lisa -- I had some suggested edits to the new paragraph describing our change in approach. The goal was to describe our new process a bit more clearly and to ensure that readers understand that in the second peer review we will be seeking input on an "approach" for using the model to derive an MCLG, not asking reviewers to apply the model themselves. Thanks. Dawn

Carrie -- This is just FYI

From: Christ, Lisa
Sent: Thursday, September 8, 2016 5:03 PM
To: Flaharty, Stephanie; Greene, Ashley; Harris, Adrienne
Cc: Perkinson, Russ; Burneson, Eric; Olson, Daniel; Messier, Dawn; Wadlington, Christina
Subject: RE: revised FRNs - yes version if we do sequential peer review

All,
The attached FRNs include edits from Eric and Dawn and are awaiting Stephanie and Peters' review. If NRDC agrees to allow more time we can proceed with the peer reviews conducted in sequence as indicated in the attached notices. If NRDC does not agree we will need to re-group on Monday.
Lisa

From: Burneson, Eric
Sent: Thursday, September 08, 2016 4:24 PM
To: Messier, Dawn <Messier.Dawn@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>

Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Perkinson, Russ <Perkinson.Russ@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

I think the notice must include an acknowledgement of the fact that we are changing plans again and switching back to a series review with a reason. I have inserted that in the attached notice. The other notice is good (I don't think we need explanation in both).

From: Messier, Dawn
Sent: Thursday, September 08, 2016 4:13 PM
To: Olson, Daniel <Olson.Daniel@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Perkinson, Russ <Perkinson.Russ@epa.gov>
Subject: RE: revised FRNs - yes version if we do sequential peer review

These look fine. (Did see a stray comma after "Versar, Inc." on page 3, after "Selection Process.")

Dawn Messier
U.S.E.P.A.
Office of General Counsel
Water Law Office
202-564-5517

From: Olson, Daniel
Sent: Thursday, September 08, 2016 3:25 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Perkinson, Russ <Perkinson.Russ@epa.gov>
Subject: FW: revised FRNs - yes version if we do sequential peer review

Eric, Dawn and Steph,

Please find attached for your review in track changes the revised perchlorate FRNs. We're sending this for your review should we get a green light to do a sequential peer review. As a reminder,

Notice #1 requests comments on the model and accompanying report, and

Notice #2 requests comment on the interim list of peer review candidates and charge.

The notices were revised based on comments from Lisa, Russ and myself.

Thanks,

Dan

From: Christ, Lisa
Sent: Thursday, September 08, 2016 12:37 PM
To: Perkinson, Russ <Perkinson.Russ@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>
Subject: revised FRNs - yes version if we do sequential peer review

Message

From:	Carroll, Gregory [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B97C09639E7F415EABCF369552152FA5-GCARRO02]
Sent:	1/29/2013 3:01:07 PM
To:	Damico, Brian [Damico.Brian@epa.gov]
CC:	Losh, Derek [Losh.Derek@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]
Subject:	Re: Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt
Attachments:	Perchlorate RFC Briefing for PG 01-28-13_GJC comments.docx

Brian:

In re-reading the materials for this morning's meeting with Peter, I flagged a number of minor points. I realize that it's likely not practical to substitute a revised version for the 11am meeting, but I point these out as changes that should be considered for the materials that are sent to OMB.

One of the edits addresses a stray word introduced by my earlier edits. The other edits address the plural nature of the word "data." (In one of TSC's briefings with Peter, he pointed the latter out as a grammar issue he looks for.)

Thanks.

Greg

Perchlorate RFC Briefing for PG 0...

From:	Brian Damico/DC/USEPA/US
To:	Daniel Olson/DC/USEPA/US@EPA, Derek Losh/CI/USEPA/US@EPA, Eric Burneson/DC/USEPA/US@EPA, Gregory Carroll/CI/USEPA/US@EPA, Meredith Russell/DC/USEPA/US@EPA, Phil Oshida/DC/USEPA/US@EPA, Maria Lopez-Carbo/DC/USEPA/US@EPA
Date:	01/28/2013 03:22 PM
Subject:	Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt

Good afternoon,

Attached are the materials for the briefing on the Preliminary Response to the Perchlorate Request for Correction with Peter Grevatt, scheduled for 11:00 am tomorrow morning. These materials have been reviewed and approved by my Acting Division Director, Phil Oshida. If you have any questions please contact myself or my Branch Chief, Eric Burneson.

Thank you for your time.

[attachment "Perchlorate RFC Briefing for PG 01-28-13.docx" deleted by Gregory Carroll/CI/USEPA/US]

Brian D'Amico
Chemical Engineer
Office of Water
United States Environmental Protection Agency
Mailcode 4607M
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
(202) 566-1069

Message

From: Olson, Daniel [Olson.Daniel@epa.gov]
Sent: 8/12/2016 3:55:22 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Helm, Erik [Helm.Erik@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
CC: Huff, Lisa [Huff.Lisa@epa.gov]; Hafez, Ahmed [Hafez.Ahmed@epa.gov]
Subject: RE: Urgent -Administrator Perchlorate Briefing
Attachments: Perchlorate in Drinking Water_8_15_16v2_amh_do.pptx

Eric,

Please find attached the revised briefing – it incorporates IQ info on slide 8, Ahmed added appendix E (IQ table), addressed OGC revisions and my concerns based on our discussion.

Thanks,

Dan

From: Burneson, Eric
Sent: Friday, August 12, 2016 11:33 AM
To: Wehling, Carrie <Wehling.Carrie@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>; Helm, Erik <Helm.Erik@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Cc: Olson, Daniel <Olson.Daniel@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>
Subject: RE: Urgent -Administrator Perchlorate Briefing

This works for me if we insert "and" for "but" and add affordability as shown below.

"SDWA requires that the enforceable MCL be set as close as feasible to the MCLG and also requires analysis of costs, benefits and affordability for any proposed MCLs"

Ahmed can you please insert.

From: Wehling, Carrie
Sent: Friday, August 12, 2016 11:30 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>; Helm, Erik <Helm.Erik@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Cc: Olson, Daniel <Olson.Daniel@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>
Subject: RE: Urgent -Administrator Perchlorate Briefing

How about "SDWA requires that the enforceable MCL be set as close as feasible to the MCLG but also requires analysis of costs and benefits for any proposed MCLs"

Caroline (Carrie) Wehling
Assistant General Counsel
Water Law Office
U.S. Environmental Protection Agency
Washington DC 20004
202-564-5492
wehling.carrie@epa.gov

From: Burneson, Eric
Sent: Friday, August 12, 2016 11:11 AM
To: Messier, Dawn <Messier.Dawn@epa.gov>; Helm, Erik <Helm.Erik@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Cc: Olson, Daniel <Olson.Daniel@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>
Subject: RE: Urgent -Administrator Perchlorate Briefing

1.Could you resend the language mentioned in item 1? Sorry but I cant seem to locate it.
2. I am concerned that this edit will loose the relationship between the MCLG and setting the MCL. I am trying to make the point that we need to have an MCLG nailed down prior to doing the cost, benefit and feasibility work.

From: Messier, Dawn
Sent: Friday, August 12, 2016 11:06 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Helm, Erik <Helm.Erik@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Cc: Olson, Daniel <Olson.Daniel@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>
Subject: Re: Urgent -Administrator Perchlorate Briefing

2 things:

1) Just checking on the language I sent you regarding the April peer review milestone in the draft CD and potential opportunities to change the agreed-upon deadlines. I thought Joel had requested the language, but don't see it in this package.

If it isn't included, maybe it'd be worth putting in the notes section so it gets mentioned?

2) We suggest the following edit on p.4:

- SDWA requires that we evaluate ~~the~~ costs, benefits, feasibility and affordability ~~of~~ in setting the enforceable Maximum Contaminant Level (MCL) ~~as close as feasible to the MCLG.~~

Please let me know if you have any questions. Thanks!

Dawn M. Messier

From: Burneson, Eric
Sent: Friday, August 12, 2016 10:48 AM
To: Helm, Erik; Christ, Lisa; Messier, Dawn
Cc: Olson, Daniel; Wehling, Carrie; Huff, Lisa; Hafez, Ahmed
Subject: RE: Urgent -Administrator Perchlorate Briefing

Here is a slightly revised version. Please use this for any further edits.

From: Helm, Erik
Sent: Friday, August 12, 2016 10:34 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Messier, Dawn

<Messier.Dawn@epa.gov>
Cc: Olson, Daniel <Olson.Daniel@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>
Subject: Re: Urgent -Administrator Perchlorate Briefing

Dan and Ahmed are working on an IQ slide

Erik C. Helm, Ph.D.
Senior Economist
U.S. Environmental Protection Agency
OW, OGWDW, SRMD
Targeting and Analysis Branch
Mailing Address:
Mailcode 4607M
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
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Room 2227N
1301 Constitution Avenue, N.W.
Washington, D.C. 20004
Email: Helm.Erik@epa.gov
Ph: 202-566-1049
Fax: 202-564-3758

From: Burneson, Eric
Sent: Friday, August 12, 2016 10:32 AM
To: Christ, Lisa; Messier, Dawn
Cc: Helm, Erik; Olson, Daniel; Wehling, Carrie; Huff, Lisa
Subject: RE: Urgent -Administrator Perchlorate Briefing

FYI we are working against a 1:00 pm deadline to submit the briefing document

---

From: Burneson, Eric
Sent: Friday, August 12, 2016 10:06 AM
To: Christ, Lisa (Christ.Lisa@epa.gov) <Christ.Lisa@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>
Cc: Helm, Erik <helm.erik@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>
Subject: Urgent -Administrator Perchlorate Briefing

Attached please find my edits to the perchlorate briefing to reflect

1. Joel's request to revise the statement about the relevance of the peer review to the NRDC lawsuit (Slide 4)
2. The SAB recommendation about modeling through to neurodevelopmental outcomes (slide 3)
3. Adding discussion of the change in IQ scores (slide 7).

Can you please let me know if you have any concerns with the attached presentation. Also please let me know if there are example results for the IQ approach that can be incorporated into Slide 8 and the appendix.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
US Environmental Protection Agency

Phone: 202-564-5250
Fax: 202 564 3760

Perchlorate in Drinking Water

Update for the Administrator

August 15, 2016

Background

- In 2005, EPA posted an RfD of 0.0007 mg/kg/day for perchlorate on the IRIS database, based on the recommendations of the NRC.
  - The point of departure for the RfD was a NOEL for inhibition of iodide uptake by the thyroid.
  - A 10x uncertainty factor was used to address sensitive life stages
- In October, 2008 EPA published a preliminary decision not to regulate perchlorate.
- In February, 2011 EPA published a final determination to regulate perchlorate in drinking water.
  - The determination was based on the RfD and *life stage specific* exposure factors for 14 different lifestages and UCMR1 occurrence data collected 2001-2005 (see Appendix A).
- SDWA requires that EPA propose a drinking water regulation within 24 months of a determination to regulate a contaminant (February, 2013).

(NRC identified the fetus of the pregnant woman as the most sensitive life stage, but also identified infants and developing children as other sensitive life stages).

Science Advisory Board Recommendations

- In 2011, EPA sought recommendations from the SAB on how to derive a Maximum Contaminant Level Goal (MCLG). The May, 2013 SAB report recommended the following:
  - "derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling (PBPK)."
  - "utilize an MOA framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition to thyroid hormone changes and finally neurodevelopmental impacts."
  - ". . . [t]his data-driven approach represents a more rigorous way to address differences in biology and exposure between adults and sensitive life stages than is possible with the default approach for deriving an MCLG."
- To address the SAB recommendations, EPA and FDA scientists have worked collaboratively since 2013 to develop a model to inform the derivation of a Maximum Contaminant Level Goal (MCLG) for perchlorate

Natural Resource Defense Council Lawsuit

- On February 18, 2016, NRDC filed a complaint in the U.S. District Court for the Southern District of N.Y. alleging that EPA failed to perform a nondiscretionary duty under SDWA (Section 1449(a)(2)) to propose and finalize a NPDWR for perchlorate.
- The NRDC seeks court-ordered proposal and final deadlines; we are currently in settlement discussions with them and we have agreed in principle to a consent decree with deadlines for proposal by March 11, 2018 and final by July 17, 2019.
  - The draft CD states that EPA "anticipates" completing the peer review by April 19, 2017 and provides that if EPA does not do so, the Agency must file a status report on the court's docket describing the expected timeline for completion of peer review
  - Based on prior discussions, NRDC would likely be open to extending the peer review completion and proposed dates, but not the deadline for the final rule.
- A critical first step in developing a drinking water regulation is identifying the MCLG.
  - SDWA requires that the enforceable MCL be set as close as feasible to the MCLG and also requires analysis of costs, benefits and affordability for any proposed MCLs
  - Convening the peer review panel this year to review methodologies to derive an MCLG is important to meeting the deadlines discussed with NRDC.
- Discussion of Legal Risk & Rationale for Settlement (OGC)

FRN for public comment on nominees, charge, products = 60 days
Contractor processes public comments and selects peer review panel, summarizes public comment and provides to panel ~ 30 days
FRN announcing peer review meeting = 30 days before the meeting

Peer Review Process

- The peer review follows the 2013 EPA *Conflict of Interest Review Process for Contractor-Managed Peer Reviews of EPA HISA and ISI* policy, based on 2004 OMB *Final Information Quality Bulletin for Peer Review* (See Appendix B for the Schedule).
- We have published two Federal Register Notices seeking public nomination of peer reviewers.
- **Next steps is to publish Federal Register Notice seeking public comment on nominated peer reviewers, the model and reports.**
  - In order to provide time for the public to submit comments on the documents, and for the peer reviewers to have time to review the draft documents and public comments we propose to publish a FRN in mid/late August.
  - To meet our prospective deadlines we propose to hold a two – day peer review panel in mid/late November.

In accordance with this peer review process, a contractor will select recognized scientific experts in PBPK, PBPK/PD and/or BBDR modeling, toxicology, environmental risk assessment and other relevant expertise, and identify a meeting venue and manage the review.

The contractor will provide panelists with the peer review charge, the documents to be reviewed, and a summary of the public comments submitted on the draft documents prior to the meeting.

Biologically Based Dose Response Model

- Consistent with SAB recommendations, EPA (ORD and OW) and FDA scientists have worked collaboratively to develop a BBDR model to predict the effect of perchlorate on the thyroid gland in lactating women, formula-fed, breast-fed infants and pregnant women and fetuses.
- The model predicts the effects of perchlorate on serum thyroid hormone concentrations (fT4) at different iodine nutrition levels and various levels of exposure to perchlorate.
  - fT4 levels can be linked to neurodevelopmental effects
- The model report will describe the model development and selection of parameters. It will also compare model results to available empirical data for fT4 levels, provide a dose-response evaluation and a sensitivity analysis.

Approaches for Use of the BBDR Model to Derive an MCLG for Perchlorate

- To derive an MCLG for perchlorate we need to apply the model to predict the perchlorate concentration in water "at which no known or anticipated adverse effects on the health of persons occur and which allows for an adequate margin of safety."
- Changes in thyroid hormone levels are not in and of themselves "adverse health effects" but the modeled fT4 levels are used to predict potential adverse health effects based on published epi data demonstrating a relationship between changes in thyroid hormone levels (fT4) and neurodevelopmental effects.
- Three adverse effects are being evaluated through this effort:
  - The change in Bayley Scales of Infant Development scores
  - The change in the percentage of pregnant women and infant populations with hypothyroxinemia
  - The change in Intelligence Quotient (IQ) scores

Example Outcomes of Draft MCLG Evaluation

- Change in Bayley Scales of Infant Development [the Psychomotor Development Index (PDI)/Mental Development Index (MDI) (See Appendix C).
  - perchlorate dose ~0.3 - 0.4 ug/kg/day (concentration of 0.5 - 2.8 ug/L) results in a 1% change in PDI
  - perchlorate dose ~ 0.5 – 0.6 ug/kg/day (concentration of 5.2 – 7.5 ug/L) results in a 1% change in PDI
- Increase in pregnant women and infant populations with hypothyroxinemia (see Appendix D)
  - perchlorate dose ~0.1 - 0.3 ug/kg/day results in a 1% increase in hypothyroxinemia among the population of 1st trimester pregnant women
- Change in IQ of offspring (See Appendix E)
  - perchlorate dose ~1.3 – 1.4 ug/kg/day (concentration of 24 - 26 ug/L) results in a 1% change in IQ.

Anticipated Stakeholder Reaction

- Industry groups (Perchlorate Study Group, American Chemistry Council); drinking water utilities; the U.S. Chamber of Commerce and the Department of Defense will likely be critical of the application of the BBDR model in sensitive iodide deficient populations as overly conservative.
- Environmental and public health groups may may be critical of the highly technical approach to modeling perchlorate in sensitive lifestages and the application of the model output to inform the MCLG
- NASA and OMB suggested an interagency review prior to public comment period.
  - We agreed to brief interagency partners in advance of publication of products for public comment and to provide their comments (along with public comments) for peer reviewers consideration.

Appendix A
Perchlorate Thresholds Presented in the 2011 Regulatory Determination

Population Estimates for PWSs That Detected Perchlorate Above Various Thresholds

Threshold[a]	Range of population served by PWSs with at least 1 detection > threshold[b] (million)
4 ug/L..................................	5.1-16.6
6 ug/L..................................	3.0-11.8
9 ug/L..................................	1.6-5.2
14 ug/L.................................	0.9-2.1
19 ug/L.................................	0.7-1.6
23 ug/L.................................	0.4-1.0

[a] All occurrence measures in this table were conducted on a basis reflecting values greater than the listed thresholds. All population estimates in this table are rounded.

[b] Population estimates are derived from UCMR 1 data which were collected between 2001 and 2003 (please add)

Appendix B
Peer Review Schedule

Task	Completion Date (Duration)
FR Notice 1 Published (solicits peer review nominations)	**March 1, 2016**
FR Notice 2 Published (solicits additional peer review nominations to expand panel)	**May 21, 2016** (30 day nomination period)
FR Notice 3 Published (announces cmt period on interim list of candidates, BBDR model, model report, MCLG report and charge questions)	**August, 2016** (30 day cmt period on interim candidate list) (60 day cmt period on model, model report, and MCLG report)
FR Notice 4 Published (announces final reviewers and pre-meeting arrangements)	**~ October, 2016** (30 days prior to panel meeting)
Combined Panel Meeting	**November, 2016**
Final Peer Review Report	**~ January, 2017** (two months after meeting)
Revised Model and Reports	**~ April, 2017** (3 months after report)

Appendix C
Key Results in Draft Products for Peer Review

Percent Change in Bayley Scales of Infant Development Scores

Perchlorate Dose (µg/kg/day) (Corresponding potential MCLG, µg/L)[a]	FT4 Level at 10th Percentile (pmol/L) for 100 µg/day individuals, unless otherwise noted	Results based on Pop et al. (1999)	Results based on Pop et al. (2003)	
		PDI at 10th Percentile (% Change)	MDI at 10th percentile (% Change)	PDI at 10th percentile (% Change)
0 (I intake = 200 µg/d)	11.3	105	101	93
0 (I intake = 100 µg/d)	9.7	90.7 (N/A)	90.5 (N/A)	79.0 (N/A)
0.2 (0[b])	9.6	90.3 (-0.5%)	90.2 (-0.4%)	78.5 (-0.6%)
0.3 (0.5)	9.6	90.1 (-0.8%)	90.0 (-0.6%)	**78.3 (-0.9%)**
0.4 (2.8)	9.5	**89.8 (-1.0%)**	89.8 (-0.8%)	**78.1 (-1.2%)**
0.5 (5.2)	9.5	89.6 (-1.3%)	**89.7 (-0.9%)**	77.8 (-1.4%)
0.6 (7.5)	9.5	89.4 (-1.5%)	**89.5 (-1.1%)**	77.6 (-1.7%)
0.8 (12.1)	9.4	88.9 (-2.0%)	89.2 (-1.5%)	77.2 (-2.3%)
1 (16.8)	9.4	88.5 (-2.5%)	88.8 (-1.9%)	76.7 (-2.8%)

a Perchlorate water concentration= total perchlorate dose - perchlorate from the diet (0.278 µg/kg/d) / ingestion rate (43 mL/kg-d). Example: (4.0 µg/kg/day - 0.278 µg/kg/d) / 0.043 L/Kg-d = 87 µg/L).

b 95th percentile for perchlorate in food (0.278 µg/kg/d) is greater than the dose (0.2 µg/kg/d).

Appendix D
Key Results in Draft Products for Peer Review

Shift in the Percentage of Pregnant Women and Infant Populations with Hypothyroxinemia

Perchlorate Dose (ug/kg/day)	Life Stage		
	1st trimester pregnant women (hX < 11.3 pmol/L)	PND 7 breastfed Infant (hX < 17.8 pmol/L)	PND 90 breastfed Infant (hx<19.1 pmol/L)
	The Additional Proportion of Individuals Falling below a Hypothyroxinemic cut point		
0.1	1%	0.5%	0
0.2	1%	1.5%	0
0.3	1%	2%	0.5%
0.4	2%	3%	0.5%
0.5	3%	3.5%	1%
0.6	3%	4.5%	1%
0.7	4%	5%	1.5%

Appendix E
Key Findings of Draft Products for Peer Review
The Impact of Altered Maternal Thyroid Hormones in Pregnant Woman and IQ in Offspring

Perchlorate Dose (µg/kg/day)	fT4 Level at 10th Percentile (pmol/L)	IQ at 10th Percentile (% Change)
0 (iodine intake = 200 µg/day; iodine replete baseline)	10.5	94 (N/A)
0 (iodine intake = 100 µg/day; low iodine baseline)	9.0	90 (N/A)
0.2	8.9	89.9 (-0.1%)
0.3	8.9	89.8 (-0.2%)
0.4	8.9	89.7 (-0.3%)
0.5	8.9	89.7 (-0.4%)
0.6	8.8	89.6 (-0.4%)
0.7	8.8	89.5 (-0.5%)
0.8	8.8	89.5 (-0.6%)
1.0	8.7	89.3 (-0.7%)
1.2	8.7	89.2 (-0.9%)

Message

From: Damico, Brian [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5293065367AB48C2BB2EBADCF992C0D6-BDAMICO]
Sent: 1/30/2013 5:23:39 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Re: Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt
Attachments: Perchlorate RFC Briefing for OMB 01-29-13.docx

Here it is. I'll drop the folder w/ the attachments off to you later today.

Perchlorate RFC Briefing for OMB ...

Brian D'Amico
Chemical Engineer
Office of Water
United States Environmental Protection Agency
Mailcode 4607M
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
(202) 566-1069

From: Eric Burneson/DC/USEPA/US
To: Brian Damico/DC/USEPA/US@EPA
Date: 01/30/2013 12:19 PM
Subject: Re: Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt

Please Send me the updated version so I can distribute to participants.

From: Brian Damico/DC/USEPA/US
To: Gregory Carroll/CI/USEPA/US@EPA
Cc: Derek Losh/CI/USEPA/US@EPA, Eric Burneson/DC/USEPA/US@EPA
Date: 01/29/2013 10:08 AM
Subject: Re: Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt

Thanks,

Those will be incorporated in the OMB version!

Brian D'Amico
Chemical Engineer
Office of Water
United States Environmental Protection Agency
Mailcode 4607M

1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
(202) 566-1069

From: Gregory Carroll/CI/USEPA/US
To: Brian Damico/DC/USEPA/US@EPA
Cc: Derek Losh/CI/USEPA/US@EPA, Eric Burneson/DC/USEPA/US@EPA
Date: 01/29/2013 10:01 AM
Subject: Re: Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt

Brian:

In re-reading the materials for this morning's meeting with Peter, I flagged a number of minor points. I realize that it's likely not practical to substitute a revised version for the 11am meeting, but I point these out as changes that should be considered for the materials that are sent to OMB.

One of the edits addresses a stray word introduced by my earlier edits. The other edits address the plural nature of the word "data." (In one of TSC's briefings with Peter, he pointed the latter out as a grammar issue he looks for.)

Thanks.

Greg

[attachment "Perchlorate RFC Briefing for PG 01-28-13_GJC comments.docx" deleted by Brian Damico/DC/USEPA/US]

From: Brian Damico/DC/USEPA/US
To: Daniel Olson/DC/USEPA/US@EPA, Derek Losh/CI/USEPA/US@EPA, Eric Burneson/DC/USEPA/US@EPA, Gregory Carroll/CI/USEPA/US@EPA, Meredith Russell/DC/USEPA/US@EPA, Phil Oshida/DC/USEPA/US@EPA, Maria Lopez-Carbo/DC/USEPA/US@EPA
Date: 01/28/2013 03:22 PM
Subject: Materials for tomorrow's 11am Perchlorate Briefing with Peter Grevatt

Good afternoon,

Attached are the materials for the briefing on the Preliminary Response to the Perchlorate Request for Correction with Peter Grevatt, scheduled for 11:00 am tomorrow morning. These materials have been reviewed and approved by my Acting Division Director, Phil Oshida. If you have any questions please contact myself or my Branch Chief, Eric Burneson.

Thank you for your time.

[attachment "Perchlorate RFC Briefing for PG 01-28-13.docx" deleted by Gregory Carroll/CI/USEPA/US]

Brian D'Amico
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE DMINISTRATOR
SCIENCE ADVISORY BOARD

May 29, 2013

EPA-SAB-13-004

The Honorable Bob Perciasepe
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: SAB Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate

Dear Acting Administrator Perciasepe:

Perchlorate is both a naturally occurring and man-made chemical that is used to produce rocket fuel, fireworks, flares and explosives. It can be present in chlorine-based disinfection products and fertilizers. The Environmental Protection Agency identified perchlorate as a potential drinking water contaminant because it may have adverse health effects and has been detected in public drinking water systems.

In 2005, at the request of the EPA and other federal agencies, the National Research Council published a comprehensive report titled *Health Implications of Perchlorate Ingestion.* The NRC concluded that perchlorate contamination could affect thyroid function by inhibiting the transport of iodide into the thyroid, which can lead to thyroid hormone deficiency. Decreased levels of thyroid hormone can have adverse effects in sensitive populations such as people with thyroid disorders, pregnant women, fetuses, and infants.

The NRC recommended that the inhibition of iodide uptake into the thyroid, a precursor non-adverse effect, be used to derive a Reference Dose for perchlorate. The NRC recommended an RfD of 0.7 μg/kg/day based on the No Observed Effect Level of 7 μg/kg/day (corresponding to a radioactive iodide uptake inhibition of 1.8 percent) and application of an uncertainty factor of 10. The uncertainty factor was applied to account for differences in sensitivity between the healthy adults in the study and the most sensitive population, namely "fetuses of pregnant women who might have hypothyroidism or iodide deficiency." The NRC concluded that this RfD should be protective of the health of sensitive populations, and acknowledged that the RfD might need to be adjusted either up or down based on the results of new research. The RfD of 0.7 μg/kg/day was adopted by EPA in 2005.

In 2009, EPA identified perchlorate as a drinking water contaminant and initiated the process to develop a Maximum Contaminant Level Goal and National Primary Drinking Water Regulation under the Safe Drinking Water Act. The MCLG is a non-enforceable goal defined under the SDWA as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."

The EPA developed a white paper that identified relevant perchlorate studies available since the publication of the NRC 2005 report. The agency also is evaluating the available physiologically-based pharmacokinetic models for perchlorate, as well as literature related to sensitive life stages that are likely to be at greater risk of adverse health effects. The EPA's Office of Water requested that the Science Advisory Board provide advice on how the agency should consider recent information on sensitive life stages, the agency's physiologically-based pharmacokinetic modeling efforts, epidemiological and biomonitoring studies, and approaches to use and integrate this information in deriving an MCLG. The SAB reviewed the recent information and EPA's white paper to develop advice on the four issue areas and provides its findings and recommendations in the enclosed report.

The SAB concludes it is important for the EPA to consider sensitive life stages explicitly in the development of an MCLG for perchlorate. The mode of action of perchlorate toxicity is well-understood. The mode of action involves the potential to disturb thyroid homeostasis by limiting the iodide uptake by the thyroid, which in turn can lead to production of less thyroid hormone. Interference with the thyroid and available thyroid hormones is known to produce adverse effects on neurodevelopment in humans, with fetuses and infants being most vulnerable. Although adverse neurodevelopmental effects of perchlorate in infants and children have not been reported in the literature, the risk of adverse effects can be reasonably inferred from perchlorate's mode of action and the known role of thyroid hormone on human brain development.

The NRC in 2005 concluded that the first adverse effect in the continuum of effects from perchlorate exposure would be hypothyroidism. In considering new information and health endpoints of potential concern, the SAB finds that the most sensitive life stages are the fetus, neonates and infants because these are the stages when thyroid-dependent brain development occurs. The development of the MCLG must consider the perchlorate exposure pathways relevant to each of these sensitive life stages, which for fetuses and breastfed infants includes exposure of pregnant and lactating women, respectively. The SAB further finds that hypothyroxinemia (i.e., low levels of thyroid hormone) is a more appropriate indicator of the potential adverse health effects than the more pronounced decreases in thyroid hormone associated with hypothyroidism. Thus, the sensitive populations EPA should consider for exposure to perchlorate are the fetuses of hypothyroxinemic pregnant women, and infants exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women.

The SAB recommends that the EPA derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling based upon its mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters. Within this MOA framework, the PBPK/PD-IUI model provides a tool for integrating exposure (e.g., different drinking water consumption scenarios), perchlorate pharmacokinetics, and dose-response relationships for perchlorate effects at the different lifestages. The SAB finds that this data-driven approach represents a more rigorous way to address differences in biology and exposure between adults and sensitive life stages than is possible with the default approach for deriving an MCLG.

The SAB concludes that the epidemiological and biomonitoring data published since the NRC 2005 report are insufficient to guide causal inference with regard to the association between perchlorate exposure and thyroid dysfunction in the sensitive life stages and populations due to the inconsistent results among the studies. As such, the current body of epidemiologic evidence cannot provide validation of a safe level of perchlorate in drinking water. Nonetheless, the SAB finds that the current epidemiology data may still be useful to support analyses to estimate perchlorate exposure of the potentially sensitive subgroups in the United States.

The SAB applauds the agency's efforts in developing models to better understand the adverse health effects of perchlorate in different life stages. To integrate the available information to develop a MCLG for perchlorate, the SAB urges the EPA to expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure. Incorporating these components into the model offers the opportunity for much greater scientific rigor in establishing quantitative relationships between perchlorate exposure and adverse effects at sensitive life stages. The SAB recognizes that full implementation of an enhanced modeling approach may take years to develop. As an interim approach, the agency could use the existing model to estimate iodide uptake inhibition and empirical observations to relate iodide uptake inhibition to thyroid hormone perturbations. Specifically, the clinical thyroid literature could be evaluated to identify the degree of iodide uptake inhibition required for onset of hypothyroxinemia in a pregnant woman. This information, together with modeling to link iodide uptake inhibition to perchlorate exposure, would provide the basis for an MCLG that addresses directly the most sensitive life stages for perchlorate effects.

The agency should incorporate the appropriate studies related to ingestion of perchlorate, pharmacokinetics of perchlorate, the effects (dynamics) of perchlorate, and dose-response relationships from all the available literature. In developing the pharmacodynamic aspect of this model, the EPA should take advantage of available data on potential adverse health effects due to thyroid hormone perturbations, regardless of the cause of those perturbations, to document and support parameters used in the model. Accordingly, the SAB concludes that these two streams of information — biology of iodide deficiency and perchlorate inhibition of iodide uptake — are complementary and sufficient for the EPA to consider specific life stage factors in deriving an MCLG for perchlorate. The SAB also notes that the specific adverse effects on brain development due to inadequate iodide uptake or low thyroid hormone levels vary at different life stages, but are especially critical during the early formative stages of brain development, when the human brain most needs thyroid hormone.

As perchlorate research continues, studies in animals may provide important insights into neurobehavioral consequences of perchlorate exposure. A physiologically-based pharmacokinetic/pharmacodynamic framework is well suited to help place these findings in the context of human perchlorate exposure.

The SAB appreciates the opportunity to provide the EPA with advice and looks forward to the agency's response.

Sincerely,

/Signed/ ***/Signed/***

Dr. David T. Allen
Chair
Science Advisory Board

Dr. Stephen M. Roberts
Chair
SAB Perchlorate Advisory Panel

Enclosure

NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to problems facing the agency. This report has not been reviewed for approval by the agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names of commercial products constitute a recommendation for use. Reports of the SAB are posted on the EPA website at http://www.epa.gov/sab.

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Science Advisory Board
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Dr. Angela Nugent, Designated Federal Officer, U.S. Environmental Protection Agency, Washington, DC

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Acronyms and Abbreviations

μg	Microgram (one-millionth of a gram)
ADHD	Attention Deficit Hyperactivity Disorder
BBDR	Biologically Based Dose Response
BW	Body Weight
DAG	Directed Acyclic Graphs
DWI	Drinking Water Ingestion
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
fT4	Free thyroxine
GW	Gestational Week
HPT	Hypothalamus-Pituitary-Thyroid
HRL	Health Reference Level
I^-	Iodide
IQ	Intelligence Quotient
IUI	Iodide Uptake Inhibition
kg	Kilogram
K_m	Michaelis Constant
L	Liter
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MOA	Mode of Action
Na	Sodium
NHANES	National Health and Nutrition Examination Survey
NIS	Sodium (Na^+)/Iodide (I^-) Symporter
NOEL	No Observed Effect Level
NPDWR	National Primary Drinking Water Regulation
NRC	National Research Council
PBPK	Physiologically-Based Pharmacokinetic
PBPK/PD-IUI	Physiologically-Based Pharmacokinetic/Pharmacodynamic-Iodide Uptake Inhibition
POD	Point of Departure
PBPK/PD	Physiologically-Based Pharmacokinetic Pharmacodynamic
PWS	Public Water System
RAIU	Radioactive Iodide Uptake
RfD	Reference Dose
RSC	Relative Source Contribution
SAB	Science Advisory Board
SDWA	Safe Drinking Water Act
T3	Triiodothyronine
T4	Thyroxine or Tetraiodothyronine
TgAb	Thyroglobulin antibody
TPOAb	Thyroid Peroxidase Antibody
TRH	Thyrotropin Releasing Hormone
TSH	Thyroid Stimulating Hormone or thyrotropin
TSH-RAb	Thyroid Stimulating Hormone Receptor Antibody
THOP	Transient Hypothyroxinemia of Prematurity
UCMR	Unregulated Contaminant Monitoring Rule

UF	Uncertainty factor
μmU	Micromolar Units

1. EXECUTIVE SUMMARY

In 2005, at the request of the Environmental Protection Agency (EPA) and other federal agencies, the National Research Council (NRC) published a comprehensive report, *Health Implications of Perchlorate Ingestion.* The NRC concluded that perchlorate could affect thyroid function because it is an anion that competitively inhibits the transport of iodide into the thyroid and that a prolonged decrease of thyroid hormone can have adverse effects in sensitive populations (people with thyroid disorders, pregnant women, fetuses and infants).

The NRC recommended the use of a precursor, non-adverse effect (i.e., inhibition of iodide uptake) to derive a Reference Dose (RfD) for perchlorate. An RfD is defined by EPA as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." The NRC recommended an RfD of 0.7 μg/kg/day, based on the No Observed Effect Level of 7 μg/kg/day (corresponding to a radioactive iodide uptake inhibition of 1.8 percent) and application of an intraspecies uncertainty factor (UF) of 10. The UF is intended to account for differences in sensitivity between healthy adults and the most sensitive population (i.e., fetuses of pregnant women who might have hypothyroidism or iodide deficiency). The NRC acknowledged that the RfD may need to be adjusted upward or downward based on future research. The RfD of 0.7 μg/kg/day was adopted by EPA in 2005.

In 2009, EPA identified perchlorate as a drinking water contaminant and initiated the process to develop a Maximum Contaminant Level Goal (MCLG) and a National Primary Drinking Water Regulation (NPDWR) for perchlorate under the Safe Drinking Water Act (SDWA). The MCLG is a non-enforceable goal defined under the SDWA as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The SDWA specifies that the enforceable Maximum Contaminant Level be set as close to the MCLG as feasible using the best available technology, treatment techniques, and other means (considering cost). The SDWA further requires that when proposing any NPDWR that includes an MCL, the Administrator must analyze "[t]he effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population."

The EPA developed a white paper that identifies recent epidemiological and biomonitoring studies and physiologically-based pharmacokinetic (PBPK) models for perchlorate. The agency is evaluating these studies, in addition to the data and information used by the NRC, to consider sensitive life stages that comprise groups within the general population that are likely to be at greater risk of adverse health effects. EPA's Office of Water requested that the SAB provide advice through responses to charge questions on how the agency should consider recent information on sensitive life stages, epidemiological and biomonitoring studies and the agency's PBPK modeling efforts. The agency also sought advice on approaches to use and integrate this information in deriving an MCLG for perchlorate.

In summary, the SAB finds that there is sufficient information to derive an MCLG for perchlorate and recommends that the agency use a mode of action (MOA) approach and physiologically-based pharmacokinetic/pharmacodynamic iodide uptake inhibition (PBPK/PD-IUI) modeling to integrate this information in a robust and transparent analysis. The SAB recognizes that this is a novel approach as compared to previous MCLG derivations that use the RfD and exposure factors. However, PBPK/PD-IUI modeling provides a more rigorous tool to integrate the totality of information available on perchlorate, and this approach may better address different life stage susceptibilities to perchlorate than the default MCLG approach.

Sensitive Life Stages

The SAB concludes that a sensitive life stage analysis is critical to derive an MCLG for perchlorate. The specific adverse effects of inadequate iodide uptake — and the consequence of low thyroid hormone levels on brain development — vary at different life stages. The fetus[1] and infant are more susceptible to perchlorate exposure effects than is the adult given that an adequate supply of thyroid hormone is essential for normal brain development. Consequently, deficits in brain development may become permanent if thyroid hormone deprivation occurs even transiently during fetal development or early life. While the effects of transient thyroid hormone deprivation on the adult brain are measurable, most signs and symptoms are reversible upon treatment with thyroid hormones. Additionally, the tissue-specific expression patterns of the sodium/iodide symporter (NIS), the molecular target of perchlorate, vary depending on life stage. Although no data exist on the long-term adverse neurodevelopmental effects of perchlorate *per se*, the human and animal data on the adverse effects of thyroid hormone perturbations (a down-stream effect from iodide uptake inhibition) on the developing brain support the need for a life stage approach. The evidence suggests that the most sensitive life stages are the fetuses, neonates and infants because these are the stages when thyroid-dependent brain development occurs. The development of the MCLG must consider the perchlorate exposure pathways relevant to each of these sensitive life stages, which for fetuses and breastfed infants includes exposure of pregnant and lactating women, respectively. Thus, the sensitive populations EPA should consider for exposure to perchlorate are the fetuses of hypothyroxinemic pregnant women, and infants exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women. This would replace "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" as defined by the NRC (2005).

Physiologically-Based Pharmacokinetic Pharmacodynamic Modeling

The EPA should utilize an MOA framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition to thyroid hormone changes and finally neurodevelopmental impacts. Within this MOA framework, the PBPK/PD-IUI model provides a tool for integrating exposure (e.g., different drinking water consumption scenarios), perchlorate pharmacokinetics, and dose-response relationships for perchlorate effects at the different lifestages. With this model, predictions for perchlorate pharmacokinetics and resulting iodide uptake inhibition can be used to address the initial steps of the MOA framework.

Extension of the current model to a PBPK/PD-IUI model to describe the pharmacodynamic changes in thyroid hormone levels would provide a key tool for linking these early events with subsequent events as reported in the literature on iodide deficiency, including changes in thyroid hormone levels and their relationship to neurodevelopmental outcomes during sensitive early life stages.

[1] Throughout this document, the term "fetus" is used to describe both the embryonic period (less than eight weeks) and the fetal period (nine weeks to term)

Epidemiological Data

The SAB concludes that the epidemiological data published since the NRC 2005 report are insufficient to guide causal inference with regard to the association between perchlorate exposure and thyroid dysfunction in pregnant women, neonates and infants or the general population. Limitations concerning study design, exposure assessment, sample size and statistical modeling have led to inconsistent results. As such, the current body of epidemiologic evidence cannot provide validation of a safe level of perchlorate in drinking water.

Nonetheless, the SAB finds that the current epidemiology data may still be useful. The available data provide support for analyses to estimate: the size of potentially sensitive subgroups in the United States; the extent to which the general U.S. population and sensitive subgroups are exposed to perchlorate, as well as other compounds with the comparable MOA (i.e., goitrogens); and the relative source contribution of perchlorate in drinking water among sensitive subgroups not addressed in the Food and Drug Administration's Total Diet Study.

Integration of Information Using PBPK/PD Modeling

The SAB recommends integrating all of the available information on perchlorate to derive an MCLG based on the MOA previously identified for perchlorate. The recommended approach relies on the use of a PBPK/PD-IUI model that associates perchlorate intake via drinking water with percent iodide uptake inhibition.

The SAB notes that the EPA developed a PBPK/PD model for perchlorate that builds on the models reviewed by the NRC. The PBPK/PD model can be used in its present form to derive an MCLG based on iodide uptake inhibition. The limitation of the model in its current state, similar to the limitations of the standard MCLG approach, in that it describes a precursor event and does not explicitly predict subsequent events or adverse outcomes. Therefore, the SAB recommends that the EPA expand the PBPK/PD approach past IUI to explicitly incorporate predictions of thyroid hormone insufficiencies. This approach will then permit assessment of the predicted exposure-response relationship for perchlorate exposure and alterations in thyroid hormone levels (e.g., decreases in serum free thyroxine (fT4)). The SAB recognizes that such an effort will require resources and time, likely on the order of one to several years. To develop an MCLG in the interim, the EPA could use the existing model to estimate IUI and develop empirical relationships for each of the steps beyond perchlorate-mediated IUI using the clinical literature. The clinical thyroid literature should be evaluated to identify the degree of iodide inhibition (percentage IUI) required for the onset of hypothyroxinemia in pregnant and lactating women and to have effects on the developing brain.

The agency should incorporate the appropriate studies related to ingestion of perchlorate, pharmacokinetics of perchlorate, the effects (dynamics) of perchlorate, and dose-response relationships from all available literature. In developing the pharmacodynamic aspect of this model, the EPA should take advantage of available data on potential adverse health effects due to thyroid hormone level perturbations, regardless of the cause of those perturbations, to document and support parameters used in the model. The SAB notes that as perchlorate research continues, studies in animals may provide important insights into neurodevelopmental consequences of perchlorate exposure.

The SAB recommendations represent an important and novel opportunity that should be implemented carefully with attention to data quality and methodological rigor. At each step, the EPA should critically evaluate available data and describe the strengths and limitations. The SAB concludes that a stepwise "integrated" approach is a logical way forward that will allow multiple sources of information to be integrated into the MCLG derivation.

2. INTRODUCTION

2.1. Background

Perchlorate is both a naturally occurring and man-made chemical that is used to produce rocket fuel, fireworks, flares, and explosives, and can be present in chlorine-based disinfection products and fertilizers. The EPA identified perchlorate as a potential drinking water contaminant because it may have an adverse health effect and has been detected in public water systems.

In 2005, at the request of EPA and other federal agencies, the National Research Council (NRC) published a comprehensive report, *Health Implications of Perchlorate Ingestion* (2005). The NRC concluded that perchlorate can affect thyroid function because it is an anion that competitively inhibits the transport of iodide[2] into the thyroid by a protein known as the sodium/iodide symporter (NIS). Significant inhibition of iodide uptake results in intra-thyroid iodine deficiency, decreased biosynthesis of key thyroid hormones – triiodothyronine (T3) and thyroxine (T4) – and increased biosynthesis of thyroid stimulating hormone or thyrotropin (TSH). The NRC also concluded that a prolonged decrease of thyroid hormone can have adverse effects in sensitive populations (e.g., people with thyroid disorders, pregnant women, fetuses and infants).

The NRC recommended the use of a precursor, non-adverse effect (i.e., inhibition of iodide uptake) to derive a RfD for perchlorate. An RfD is defined by EPA as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." The NRC recommended an RfD of 0.7 μg/kg/day, based on the No Observed Effect Level of 7 μg/kg/day (corresponding to a radioactive iodide uptake inhibition of 1.8 percent) and application of an intraspecies uncertainty factor (UF) of 10. The UF is intended to account for differences in sensitivity between healthy adults and the most sensitive population (i.e., fetuses of pregnant women who might have hypothyroidism or iodide deficiency). The NRC acknowledged that the RfD may need to be adjusted upward or downward based on future research. The RfD of 0.7 μg/kg/day was adopted by EPA in 2005 (U.S. EPA 2005).

The EPA has initiated the process to develop a Maximum Contaminant Level Goal (MCLG) and National Primary Drinking Water Regulation (NPDWR) for perchlorate under the SDWA (U.S. EPA 2011). The MCLG is a non-enforceable goal defined under the SDWA (§1412.b.4.B) as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." For perchlorate, the NPDWR likely will specify an enforceable Maximum Contaminant Level (MCL) and monitoring and reporting requirements for public water systems. The SDWA (§1412.b.4.B and D) specifies that the enforceable MCL be set as close to the MCLG as feasible using the best available technology, treatment techniques, and other means (considering cost).

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[2] Molecular iodine is rapidly converted into iodide following ingestion, is efficiently absorbed throughout the gastrointestinal tract, and is prevalent in biological and physiological reactions (Welt and Blythe 1970). Trace level measurement in biological and physiological samples (e.g.,, milk, serum, urine) usually measures iodine (Shelor and Dasgupta 2011). This report uses either iodide, iodine, or the specific iodine measurement as cited in the studies to be consistent with the referenced authors' description.

EPA generally derives an MCLG using the following formula as a default:

$$\textbf{MCLG } (\mu g/L) = \frac{\textbf{RfD x BW}}{\textbf{DWI}} \textbf{ x RSC}$$

Where:

RfD is the reference dose for a contaminant (µg/kg/day).
BW is body weight in kg. A default body weight (70 kg) is typically used.
DWI is drinking water ingestion rate in L/day. A default intake (2 L/day) is typically used.
RSC is the relative source contribution. The RSC is derived as the percentage of the RfD remaining for drinking water after other sources of exposure to perchlorate (e.g., food) have been considered (U.S. EPA 2012). The EPA is relying on a Total Diet Study developed by the Food and Drug Administration (FDA) for perchlorate (Murray et al. 2008).

The regulatory schedule established by the SDWA requires EPA to publish a proposed MCLG and NPDWR within 24 months of making a determination to regulate a contaminant and promulgate a final regulation within 18 months of the proposal. The SDWA further requires that when proposing any NPDWR that includes an MCL, the Administrator must analyze "[t]he effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population."[3]

EPA developed a white paper (2012) that identifies available information published since the NRC report (2005). The white paper presents epidemiological studies, biomonitoring studies and physiologically-based pharmacokinetic (PBPK) modeling[4] that the agency is evaluating, in addition to the data and information used by the NRC, to consider sensitive life stages that are likely to be at greater risk of adverse health effects from perchlorate exposure than the general population.

EPA's Office of Water requested the Science Advisory Board's (SAB) advice on how best to consider the sensitive life stages, recent biomonitoring data, epidemiological studies, and PBPK modeling, and to integrate this information in deriving an MCLG for perchlorate. The SAB formed an ad hoc panel, the Perchlorate Advisory Panel, to perform this task. The Panel met on July 18-19, 2012, to hear EPA technical presentations, public comments on the draft White Paper and discuss responses to the Charge to the SAB. The Panel held follow-up teleconferences on September 25, December 5, and December 7, in 2012 to discuss their draft responses to the EPA Charge questions The Panel's draft report was considered by the Chartered SAB on March 29, 2013. The Chartered SAB unanimously approved the report with slight modifications to provide additional citations to support infants as a sensitive

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[3]SDWA uses the term subpopulation to refer to groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other groups that can be identified and characterized and are likely to experience elevated health risks. In 2005 EPA started using the term life stages to refer to age-defined groups. All life stages are subpopulations but not all subpopulations are life stages. In this document, the term life stage is used predominantly because of the focus on infants and very young children.

[4] The EPA white paper and Charge to the SAB refer to the current model as a PBPK model. The SAB notes that the current model predicts iodide uptake inhibition, which is a pharmacodynamic step in the mode of action. This report refers to the model as PBPK/PD.

population, clarify the potential use of epidemiological data, and clarify how results of PBPK-PD models could be considered to estimate adverse effects.

2.2. Charge to the Science Advisory Board

The EPA Charge to the SAB requests advice and recommendations on approaches to derive an MCLG for perchlorate. The EPA identified recent studies on life stage information for infants and children, epidemiologic and biomonitoring data since the NRC report (2005), and physiologically-based pharmacokinetic modeling that addresses iodide uptake inhibition and the decreased synthesis of thyroid hormones. The agency is seeking advice on how to consider these studies and models in terms of different life stages and adverse effects, approaches to include the information in deriving an MCLG, and what are the strengths and limitations of the biomonitoring and epidemiological studies. The Charge also asks the SAB how best to integrate the totality of available information to derive a health-protective MCLG. Charge questions are included at the beginning of each section of this report and the full Charge is included as Appendix A.

3. RESPONSE TO CHARGE QUESTIONS

The first three sets of specific charge questions focus on how the EPA should consider various life stage factors, PBPK modeling, and epidemiological and biomonitoring studies published since the NRC report, *Health Implications from Perchlorate Ingestion* (2005), to develop an MCLG. A fourth set of charge questions addresses the related issue of how this and other available information should be integrated into development of a health-protective MCLG and how reductions in adverse health effects from lowering perchlorate concentrations in drinking water can be estimated.

In responses to charge questions on different life stages, the SAB identified the most sensitive life stages as the developing child — fetus[5], neonate and infant — because these are stages when thyroid-dependent brain development occurs. The development of the MCLG must consider the perchlorate exposure pathways relevant to each of these sensitive life stages, which for fetuses and breastfed infants include exposure of pregnant and lactating women, respectively. Thus, the sensitive populations that EPA should consider for exposure to perchlorate are the fetuses of hypothyroxinemic pregnant women, and infants exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women. Iodide deficiency, decreased thyroid hormone biosynthesis, and other key factors were identified as important considerations in addressing perchlorate health risk. The SAB also noted the agency's progress in using PBPK/PD models to better understand the potential impacts of perchlorate exposure during different life stages. The PBPK/PD models characterize the dose-response relationship between perchlorate exposure in food and water and perchlorate concentrations in plasma and tissue and resulting IUI. By selecting a POD for IUI, the current models could be used to develop an MCLG. The models could be further enhanced to encompass more of the MOA, characterizing the dose-response relationship between the dose of perchlorate and IUI and inhibition of early life thyroid hormone production, and extending finally to neurodevelopmental endpoints. At each stage of model expansion, selection of an appropriate POD would allow development of a more refined MCLG. In review of the epidemiological and biomonitoring studies, the SAB identified data of value in assessing risk of perchlorate exposure, but found that limitations and inconsistent results in the epidemiological and biomonitoring studies precluded their applicability to deriving the MCLG.

When considering how to integrate the disparate information and analyses into the derivation of an MCLG, the SAB found that the default algebraic approach provides limited ability to address the various exposure and biological factors affecting sensitivity to perchlorate at different life stages. The SAB concluded that, from a scientific standpoint, it would be more appropriate to base the MCLG derivation on the perchlorate mode of action, using PBPK/PD modeling to relate perchlorate concentrations in drinking water to biological effects rather than the default approach.

3.1. <u>Sensitive Life Stages</u>

<u>*Charge Questions:*</u>
There are currently no data available to directly link perchlorate to neurobehavioral effects in infants and children. How should EPA consider the following life stage factors in deriving an MCLG?

- *Life stage specific differences in body weight and food and drinking water intake;*

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[5] Throughout this document, the term "fetus" is used to describe both the embryonic period (less than eight weeks) and the fetal period (nine weeks to term)

- *Differences in greater severity and permanence of potential adverse effects in neonates, infants and young children compared to adults;*

- *Shorter half-life and lower reserves for thyroid hormone in infants compared to adults; and*

- *Intrauterine exposure to perchlorate and impact on thyroid status in fetuses.*

3.1.1. Rationale for Considering Life Stages in Deriving an MCLG

The SAB finds that there is a critical need to consider sensitive life stages in deriving an MCLG for perchlorate. The SAB recognizes that studies directly linking perchlorate to neurobehavioral effects in infants and children are lacking. However, the SAB notes that there are scientifically sound human clinical and rodent toxicology reports that describe the biology linking iodide deficiency, changes in thyroid hormone production and developmental and neurobehavioral effects. The mechanisms of perchlorate inhibition of NIS-mediated iodide uptake into the thyroid are also well documented (Dohan et al. 2007; Tran et al. 2008; Paroder-Belenitsky et al. 2011). Accordingly, the SAB concludes that these streams of information — neurobiology of iodide deficiency, thyroid hormone deficiency and perchlorate inhibition of iodide uptake — are complementary and sufficient for the EPA to consider specific life stage factors in deriving an MCLG for perchlorate. The SAB also notes that the specific adverse effects on brain development from inadequate iodide uptake and low thyroid hormone levels vary at different life stages, but are especially critical during the early formative stages of brain development.

The thyroid hormones T3 and T4 are the only iodine-containing hormones in the body. Dietary iodide is transported from the bloodstream into the thyroid via the NIS, an intrinsic plasma membrane protein consisting of 643 amino acids (Dai et al. 1996; Smanik et al. 1996; Riesco-Eizaguirre and Santisteban 2006). This transport process is the first and key rate-limiting step in the biosynthesis of T3 and T4. NIS is expressed in the salivary glands and stomach, two tissues where active iodide transport also takes place. Notably, NIS is also highly expressed in the placenta and lactating breast, allowing iodide to be supplied to the fetus and the breast-feeding infant (Tazebay et al. 2000; De La Vieja et al. 2000; Dohan et al. 2003).

To synthesize these hormones, iodide is transported by NIS from the bloodstream into the interior of the thyroid cell and then oxidized and covalently incorporated into specific tyrosyl residues on a large precursor molecule called thyroglobulin in the colloid of the thyroid (Carrasco 1993). After endocytosis of iodinated thyroglobulin and proteolysis, the resulting thyroid hormones, T3 and more abundant T4, are transported from the thyroid via the bloodstream to various essential target organs. One primary target organ is the brain, which has a well-defined need for thyroid hormones for its normal development (Zoeller and Rovet 2004).

A deficit of thyroid hormones leads to inadequate brain development, which ultimately may cause intellectual and behavioral impairments in the developing child (Morreale de Escobar et al. 2000) and continue throughout life (Oerbeck et al. 2003; Kempers et al. 2006). Since the iodide needed for T3 and T4 production cannot be synthesized within the body, iodide must be obtained through the diet, and this requires a constant and sufficient supply of iodide to ensure normal thyroid function (Carrasco 1993). In addition, the need for iodide is substantially higher during pregnancy to support the increased production of maternal thyroid hormones that occurs during this period (Glinoer 2004). Children who experienced iodide or thyroid hormone insufficiency during early critical stages of brain development (viz., gestation and infancy) are at risk of neurological, mental, and growth impairments (Glinoer and Delange 2000; Glinoer and Rovet 2009). Importantly, repletion of thyroid hormone outside these critical windows of time may be insufficient for reversal of these impairments (Porterfield and Hendrich 1993; Bernal 2005).

Perchlorate inhibits iodide uptake and therefore interferes with thyroid hormone production. Perchlorate acts by specifically inhibiting NIS-mediated transport of iodide into the thyroid, placenta, lactating breast, and all other NIS-expressing tissues in a concentration-dependent manner. Although perchlorate has long been known to act as a competitive NIS inhibitor, recent studies show that perchlorate is actually an actively transported NIS substrate (Dohan et al. 2007; Tran et al. 2008; Paroder-Belenitsky et al. 2011). Thus, in the presence of perchlorate, less iodide may be available for thyroid hormone biosynthesis. The extent of inhibition of iodide uptake is dependent upon the relative concentrations of the two anions and their respective Michaelis constants (K_m) for transport. Consequently, a primary downstream effect of perchlorate exposure is reduction in the levels of T3 and T4.

Although the critical evidence is lacking to directly link perchlorate to altered brain development in humans, animal studies show that exposing pregnant dams to perchlorate is associated with compromised brain development in their progeny (Gilbert and Sui 2008). In humans, studies of children born to mothers with either iodide or thyroid hormone insufficiencies provide complementary evidence. Specifically, the offspring of women who were iodide deficient during pregnancy show cognitive and behavioral impairments (Pharoah et al. 1984; Vermiglio et al. 2004). These impairments could be ameliorated by giving mothers iodide supplementation from the first trimester (Berbel et al. 2009; Velasco et al. 2009; Glinoer and Rovet 2009). Iodide supplementation begun in later trimesters did not show that the impairments were ameliorated, suggesting a critical and early window of iodide sufficiency for fetal brain development. Similarly, children born to women with clinical (Smit et al. 2000; Mirabella et al. 2000) or subclinical hypothyroidism (Haddow et al. 1999) show reduced intelligence quotient (IQ), selective cognitive deficits, and behavioral abnormalities compared with children whose mothers had normal pregnancy TSH levels. Haddow et al. (1999) also showed that the degree of compromised neurodevelopmental outcomes was less in the subgroup of children whose mothers reportedly took thyroid hormones exogenously in pregnancy; these findings demonstrate the importance of preventing any degree of hypothyroidism, regardless of its cause, in pregnancy.

Perhaps most critical are the findings from studies examining the effects of isolated maternal hypothyroxinemia, defined as a free thyroxine (fT4) value in the lower end of the normal range with normal levels of TSH. This research has involved a variety of cutoffs to signify maternal hypothyroxinemia ranging from fT4 below the 10^{th} or 5^{th} percentiles to below the 2.5^{th} percentile (Moleti et al. 2011), with the former percentiles being used to investigate neurodevelopmental outcomes and the latter the incidence and effects on pregnancy (e.g., Casey et al. 2005). Children exposed gestationally to maternal hypothyroxinemia (without hypothyroidism) show reduced levels of global and specific cognitive abilities, as well as increased rates of behavior problems including greater dysregulation in early infancy and attentional disorders in childhood (Man et al. 1991; Pop et al. 1999; Pop et al. 2003; Kooistra et al. 2006). Notably these effects are correlated with both degree (Pop et al. 1999; Henrichs et al. 2010) and duration (Pop et al. 2003) of maternal hypothyroxinemia. The Henrichs (2010) study, which stratified children into severe ($<5^{th}$ percentile) and mild ($5\text{-}10^{th}$ percentile) maternal hypothyroxinemia subgroups, showed that while effects were stronger and broader in the severe subgroup, the mild subgroup still showed delayed language development, thus suggesting that any factor that lowers maternal fT4, even slightly, can affect the offspring.

Two lines of evidence suggest that the infant also may be vulnerable to perchlorate exposure: infants born preterm who experience transient hypothyroxinemia of prematurity (THOP) and children with congenital hypothyroidism. THOP arises because the fetal thyroid system is immature if a child is born preterm and the late-gestational maternal iodine and thyroid hormone supplies are no longer available (Vulsma et al. 1989; Morreale de Escobar et al. 2008; LaGamma 2008; Simic and Rovet 2010). Follow-up studies of THOP report reduced IQ (Lucas et al. 1996), impaired visual skills (Rovet and Simic 2008) and an increased incidence of neurological dysfunction and school failure (Den Ouden et al. 1996), cognitive disabilities (Simic and Rovet 2010), cerebral palsy (Reuss et al. 1996) The effects were most severe in those with the lowest levels of thyroid hormone in the neonatal period (Simic and Rovet 2010). In an animal model of prematurity, Berbel and colleagues showed that manifestations of low thyroid hormone levels on the neural substrates of abilities are affected in THOP (Berbel et al. 2010). Congenital hypothyroidism, which arises from a defect in thyroid gland formation or function or its central regulation by the hypothalamus and pituitary (Rovet and Daneman 2003), is associated with mental retardation and severe behavior problems if untreated in the newborn period (Rovet 1992). Since the advent of newborn screening for congenital hypothyroidism, affected children undergo a far briefer period of thyroid hormone deficiency than before, showing IQ reductions of about 6-7 points (Rovet 2005), and a variety of subtle selective neurocognitive deficits (Rovet and Daneman 2003), the nature of which reflect the timing and duration of being without thyroid hormone. While children with congenital hypothyroidism demonstrate that thyroid hormone is essential throughout infancy, the exact time when the brain is no longer critically dependent on an adequate supply of thyroid hormone is unknown but estimated to be two years of age, when most essential neurodevelopment is complete.

Recommendation:

The SAB recommends that the EPA consider sensitive life stages in developing an MCLG for perchlorate. The SAB finds that the most sensitive life stages are the fetus, neonates and infants because these are the stages when thyroid-dependent brain development occurs. The development of the MCLG must consider the perchlorate exposure pathways relevant to each of these sensitive life stages, which for fetuses and breastfed infants include exposure of pregnant and lactating women, respectively. Thus, the sensitive populations that EPA should consider for exposure to perchlorate are the fetuses of hypothyroxinemic pregnant women, and infants exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women. This would replace "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" as defined by the NRC (2005).

3.1.2. Life Stage Specific Differences in Body Weight and Intakes

Specific differences in body weight, food intake, and drinking water consumption are important factors for the understanding of perchlorate-induced iodide uptake inhibition (IUI) at different life stages. The factors specified in this subpart of the charge question are a reflection of the default formula applied by the EPA to develop an MCLG from an RfD, which is frequently applied for chronic toxicities for which adult body weight and intake dominate exposure calculations. The challenge in the case of perchlorate is that the developing nervous system is of interest and thus, exposures during specific periods of development (e.g., *in utero* or early postnatal) need to be considered. During these periods, many biological changes occur beyond body weight and food or water intake. For example, evidence is available from the literature on other drug and chemical exposures showing differing absorption and metabolism rates with age and body weight (Kearns et al. 2003; Bartelink et al. 2006; Anderson and Lynn 2009). Since NIS is expressed in tissues other than the thyroid, such as the salivary glands, stomach, lactating breast, and placenta, one might anticipate developmental differences in pharmacokinetics and pharmacodynamics for perchlorate and iodide uptake inhibition.

Recommendation:

The SAB notes that the EPA developed a PBPK/PD model that considers life stage differences in thyroid NIS inhibition and has continued to develop this model (U.S. EPA 2009, 2012). Because the SAB recommends using the PBPK/PD modeling approach (see Sections 3.2 and 3.4), life stage specific differences in body weight, food, and drinking water intakes have been and should be explicitly incorporated in the modeling of each life stage and documented. Additionally, differences in other parameters characterizing the biological system in the model, such as organ weights (volumes), blood flows, or NIS activity have been incorporated and over time may need to be updated if more information becomes available in the scientific literature.

The SAB acknowledges that NIS expression is accounted for in different tissues and at different stages of development in the current PBPK/PD model for radioactive iodine uptake (RAIU) inhibition calculations (see Section 3.2). In addition, the current PBPK/PD model addresses the movement of perchlorate into relevant organs (i.e., lactating breast, mammary gland, placenta, and thyroid gland of the mother and the fetus) that can interfere with the availability of thyroid hormones for brain development. In the longer term, new models for the hypothalamic pituitary thyroid axis need to also include these same competitive inhibition equations for both iodide and perchlorate for NIS-bearing organs or tissues.

3.1.3. Differences in Potential Adverse Effects to Neonates, Infants and Young Children

The SAB finds that neonates, infants and children are significantly more sensitive than are adults to the potential effect of decreased thyroid hormone levels on brain development, and that these effects are significantly longer lasting in the child population.

It is well established that thyroid hormones are essential for normal brain development (Bernal and Nunez 1995; Anderson 2001). A broad and diverse literature, based primarily on rodents, has shown that T3 and T4 are translocated into the brain through the blood-brain barrier by specific transporters (Patel et al. 2011). From there, T4 enters glia, where it is metabolized to T3 by local deiodinases. The resulting T3 is then transported via specific transporters (Kester et al. 2004) into target brain cells, where it binds to nuclear thyroid hormone receptors and regulates expression of key brain genes fundamental to critical neurodevelopmental processes (Anderson et al. 2003; Bernal 2007). These processes include neurogenesis, neuronal migration, axon and dendritic growth, synaptogenesis, and myelination (Chan and Rovet 2003). Thyroid hormones regulate these developmental processes throughout gestation and early life (Zoeller and Rovet 2004). The temporal sensitivity of thyroid hormone deprivation differs depending on brain region. Therefore, the consequences of thyroid hormone insufficiency, regardless of cause, will vary depending on when the deficiency occurs (Royland et al. 2008). Furthermore, since different brain regions vary in development as to their timing of need for thyroid hormone (Thompson and Potter 2000; Morreale de Escobar et al. 2004), the specific consequences of thyroid hormone insufficiency or iodide deficiency will also differ regionally within the brain (Schweizer et al. 2008). Importantly, the adult brain is also sensitive to hypothyroidism with observed changes in mood and cognition, and linkage to neuropsychiatric symptoms (Bauer et al. 2008; Samuels 2008). However, in adults most signs and symptoms are reversible upon treatment with thyroid hormones, indicating that most effects of hypothyroidism on the adult brain are not permanent (Bauer et al. 2008) and are therefore less severe compared to reduced thyroid hormone levels during brain development.

Finally, as human neurodevelopment occurs along a continuum through gestation to childhood, it is also important to consider that the human thyroid develops during gestation and does not begin secreting thyroid hormones in limited amounts until the fourth month of gestation (Ballabio et al. 1989; Obregon et al. 2007), with earlier embryonic and fetal brain development being totally reliant on the maternal thyroid hormone supply (Kempers et al. 2004).

There is diversity among the multiple markers in the developing brain that are sensitive to alterations in thyroid hormone concentrations during development, as revealed in both human and animal research (Bernal 2005; Ahmed et al. 2008; Gilbert et al. 2012). The molecular basis of thyroid hormone action is the regulation of gene transcription. Target genes can be regulated directly through receptors bound to gene regulatory regions, or indirectly through thyroid hormone-dependent changes in regulatory gene expression. Alterations in the expression of target genes in the brain may also be associated with downstream changes in, for example, brain cytoarchitecture, cellular function, morphology, physiology, and behavior (Bernal 2005; Ahmed et al. 2008; Gilbert et al. 2012). Therefore, some Perchlorate Advisory Panel members thought that a wide range of associated downstream markers could be used to indicate thyroid hormone insufficiency during development provided they are well documented as directly or indirectly regulated by thyroid hormone. The use of new neuroimaging approaches allows researchers to investigate these effects in humans (Wheeler et al. 2011, 2012). Changes in any of these validated markers could be considered evidence of a precursor event to an adverse effect when assessing the potential impact of perchlorate on iodide uptake inhibition and circulating and tissue thyroid hormone levels during brain development. Importantly, changes in these markers will vary according to the stage of development and time period over which the thyroidal perturbation occurs. Finally, observed changes may be permanent or transient depending upon the developmental time frame of thyroid hormone repletion.

The SAB recognizes that it is essential to obtain robust data in order to best assess the long-term effects of perchlorate exposure on thyroidal iodide uptake and resultant impact on thyroid function, as measured by TSH and free T4 levels, in both human and animal models. In contrast to the dearth of studies of perchlorate effects on neurodevelopment, the literature on iodide deficiency, maternal hypothyroxinemia, THOP, and congenital hypothyroidism is robust and provides key data identifying the range of thyroidal perturbation attributable to reductions in iodide availability to the thyroid gland or to thyroid hormone production itself. The importance of these broad areas of research for interpreting the results of perchlorate studies is that the ultimate mechanism of perchlorate toxicity is known: perchlorate limits the access of iodide to the thyroid, which in turn means less thyroid hormone for the developing brain. These data can be compared to the known neurodevelopmental effects of mild, moderate and severe iodide deficiency on human and animal brain development. The SAB finds that while the currently available studies are insufficient to draw unequivocal conclusions regarding the impact of perchlorate exposure on human brain development, studies on iodide deficiency and maternal low thyroid hormone levels are invaluable. Indeed, recent studies based on newly available neuroimaging data show a direct impact of these deficiencies on the human brain (Willoughby 2011; Wheeler et al. 2011, 2012).

3.1.4. Thyroid Hormone Reserve Differences

It is reported that fetuses and infants have lower reserves of thyroid hormones (van De Hove et al. 1999; Savin et al. 2003) and those thyroid hormones have shorter half-lives compared to half-lives in adults (Brent 2010). However, the key evidence linking these features to perchlorate levels, iodide levels, and outcome is lacking. It is possible that gestational exposure to perchlorate can have an impact on fetal thyroid hormone production and brain development, without necessarily altering maternal thyroid hormone levels, and this effect can be compounded by iodine insufficiency (Zoeller 2004; Brent 2010). In addition, while the fetus can employ compensatory mechanisms to protect from reduced thyroid hormone levels, recent animal studies have found that while mild to moderate thyroid hormone deficiency induces compensation, it may not be sufficient to fully protect the brain from reduced circulating thyroid hormones when exposed to goitrogens (Sharlin 2010; Bastian 2012).

A study by Blount et al. (2009) measuring perchlorate and iodine levels from multiple compartments (e.g., maternal urine, maternal serum, cord blood serum, amniotic fluid) in women undergoing cesarean section surgery showed that at time of birth, perchlorate levels were high, including in cord blood, but there was no evidence of either inhibition of iodine transport across the placenta or impact on infant growth. While the absence of effect may be due to the high levels of iodine in the study population, since most women were taking iodine-fortified prenatal vitamins, it is also possible that later developmental effects may become evident but are more subtle than those measured by Blount (Brent 2010) and that perchlorate effects will be observed in breast milk once the infant starts to feed (Blount et al. 2009). Nevertheless, the EPA should consider lower thyroid hormone reserves and shorter retention or half-lives in comparison with the non-pregnant adult.

Recommendation:
When determining safe levels of perchlorate in drinking water, the EPA should consider the shorter half-life and lower reserves of thyroid hormone and metabolic differences in each of the specific sensitive life stages evaluated. It is critical that the EPA consider these key features in making comparisons with the non-pregnant adult, based on the Greer et al. study (2002). Additionally, this issue may be studied in animals using appropriate experimental designs.

3.1.5. Intrauterine Exposure to Perchlorate and Thyroid Status Impact in Fetuses

The SAB finds that intrauterine perchlorate exposure has the potential to affect the developing embryo and fetus in several ways. First, this exposure can lead to less iodide for the fetal thyroid. In addition, gestational perchlorate exposure can mean less maternal thyroid hormone because her iodide supply has been reduced. In early pregnancy, prior to the onset of fetal thyroid function, the main disruption will be less maternal thyroid hormones. Later in gestation, when the fetal thyroid is functioning and needs iodide to make its own thyroid hormones, both maternal and fetal supplies of thyroid hormone will be reduced. This hypothyroxinemia (i.e., low thyroid hormone levels) will likely have an impact on the embryonic and fetal brain, affecting those processes, structures and pathways that have the highest need for thyroid hormone at the particular time. In addition, maternal hypothyroxinemia in pregnancy can lead to adverse reproductive and pregnancy outcomes, including increased rates of preterm delivery (Casey et al. 2005).

Although the fetal thyroid develops in the first trimester of pregnancy, it does not secrete thyroid hormone until the second trimester and is not centrally regulated by the hypothalamus and pituitary (which secrete thyrotropin releasing hormone (TRH) and TSH) until the third trimester (Thorpe-Beeston et al. 1991; Obregon et al. 2007). The fetal thyroid continues to grow throughout gestation (Costa et al. 1986), as does its capacity to secrete hormone (Williams et al. 2004). Autopsy evidence indicates that the fetal brain appears to need thyroid hormone very early in gestation, including in the embryonic nervous system, given findings of thyroid hormone receptors and measurable quantities of maternally derived thyroid hormone in embryonic brain (Kilby et al. 2000; Kempers et al. 2004). Since substantial quantities of maternal thyroid hormone are also observed both in fetal compartments throughout gestation (Calvo et al. 2002) and in neonatal serum at term (Vulsma et al. 1989), an adequate maternal supply of thyroid hormone to the fetus is necessary until the end of pregnancy. The fetal thyroid T4 stores are reduced in comparison to the adult suggesting the fetal thyroid is less resilient to prolonged thyroidal perturbation (van den Hove et al 1999; Savin at al. 2003; Zoeller and Rice 2004). After birth, small amounts of thyroid hormone may be transferred from the mother to the infant via breast milk

(Rovet 1990). This dual maternal–fetal/child system typically allows for normal brain development, unless either the maternal or the child thyroid hormone supplies are inadequate.

Women with inadequate levels of thyroid hormone during pregnancy due to hypothyroidism or hypothyroxinemia are unable to provide the fetus with sufficient thyroid hormone (Moleti et al. 2011). It is well established that offspring of these women are at risk for poor outcomes, including mild to severe IQ reductions, specific cognitive and motor deficits, learning disabilities and behavioral problems (Man et al. 1991; Haddow et al. 1999; Pop et al. 1999; Smit et al. 2000; Mirabella et al. 2000; Kooistra et al. 2006; Henrichs et al. 2010). Morreale de Escobar et al. (2004) found that maternal hypothyroxinemia, when occurring during gestation, has been associated with neurological impairment. Furthermore, iodide deficiency during pregnancy and early neonatal life is also associated with impaired development of the brain and suboptimal outcomes (Pharoah et al. 1984; Vermiglio et al. 2004) since pregnant and lactating women from iodide-deficient areas provide insufficient iodide through the placenta or breast milk to their offspring (Zimmerman 2009). Finally, children who are thyroid hormone-deficient due to congenital hypothyroidism or iodide deficiency also show suboptimal to poor neurodevelopmental outcomes, which reflect directly on the severity and duration of the thyroid hormone or iodide deficiency (Rovet and Daneman 2003; Vermiglio et al. 2004). Because most thyroid hormone-mediated brain development only becomes complete by the age of two years, the fetus, infant and very young child are especially vulnerable to the effects of both thyroid hormone and iodide deficiency.

Since perchlorate inhibits iodide transport into the thyroid, exposure to perchlorate can have a direct impact on the maternal thyroid, the fetal thyroid, and the child's thyroid throughout its development. Perchlorate is likely to have a downstream effect on the developing brain similar to that observed in studies of iodide and thyroid hormone deficiency. However, no data exist in humans directly examining the relation between perchlorate exposure, its thyroidal impact, and the developing brain. Nevertheless, a recent study with perchlorate-exposed rodent dams and offspring showed specific impairments of hippocampal synaptic transmission, even at low doses that only minimally affected the dam and pup thyroid axis (Gilbert and Sui 2008).

From studies of the developing human thyroid, it is expected that in early pregnancy, when the embryo or fetus rely entirely on the maternal supply of thyroid hormone to meet the early brain needs, perchlorate exposure will lead to reduced thyroid hormone from the mother, and this will have an impact on the brain functions that are developing at this early time. Once the fetal thyroid starts to function in the second trimester, the fetus will require its own supply of iodide in order to make thyroid hormone. Thus, perchlorate actively transported through the placenta via NIS may block fetal iodide uptake into the thyroid and lead to lowered thyroid hormone production. This lowered fetal thyroid hormone production, along with the already reduced maternal thyroid hormone supply, will likely lead to a state of fetal hypothyroxinemia throughout pregnancy. However, the critical data on these effects do not exist.

Perchlorate exposure after birth, through either water-based formula preparations or breast milk, can reduce the infant's capacity to synthesize thyroid hormone by blocking its iodide supply and lowering its capacity to produce thyroid hormone. Notably, breast-fed infants exposed to perchlorate may also receive less thyroid hormone in the milk than non-exposed infants because their mother's thyroid hormone production has been compromised by her reduced iodide supply due to the perchlorate (Sack et al. 1981; Rovet 1990). Older infants and young children may be affected by perchlorate in dairy milk and certain foods, in addition to perchlorate in drinking water.

Overall, these findings signify that perchlorate exposure at different sensitive life stages may lead to reduced thyroid hormone, which in turn can adversely affect brain development in gestation and infancy. Moreover, the effects may be particularly profound if exposure occurs during a critical window of development. Although some literature examining perchlorate levels in relation to maternal and neonatal thyroid hormone levels does exist, the findings are contradictory. Furthermore, the evidence is often limited methodologically and/or the statistical approach is inadequate (see Section 3.3.2). Nevertheless, the findings show that the fetus and infant are definitely more susceptible to effects of perchlorate exposure than is the adult. Exposure may be more harmful for fetuses and infants given that their brains are undergoing rapid thyroid hormone-dependent development, in contrast to the fully developed adult brain. Although no data exist on the long-term adverse neurodevelopmental effects of perchlorate *per se*, the data on the adverse effects of iodide deficiency and thyroid hormone perturbations (a downstream target) on the developing brain justify the need for a life stage approach to setting an MCLG.

Recommendation:
It is important that future studies monitor maternal iodide and thyroid hormone levels throughout pregnancy in relation to perchlorate exposure and reproductive/pregnancy outcomes. Future studies may also measure fetal integrity directly by obtaining measurements such as fetal heart rate, ultrasound measures of fetal thyroid, fetal movement, growth and response to stimulation (Allen and Lipkin 2005). Additionally, in light of advances in neuroimaging of the fetus and neonate, future research could obtain direct measurements of the fetal brain in relation to perchlorate exposure at different levels.

3.2. Physiologically Based Pharmacokinetic Modeling

Charge Question:
What are the strengths and limitations of the two PBPK model results described in this effort?

3.2.1. Considering PBPK Modeling to Derive an MCLG for Perchlorate

Charge Question:
How should EPA consider PBPK modeling to derive an MCLG for perchlorate?

The NRC committee made a recommendation to use inhibition of iodide uptake by the thyroid arising from competitive inhibition of the NIS by perchlorate as the first step in the MOA for perchlorate leading to all subsequent events (See Figure 1) (NRC 2005). The NRC indicated this effect of perchlorate was relevant for perchlorate risk assessment and provided a health-protective and scientifically valid approach, which has been incorporated by EPA in the derivation of the perchlorate RfD of 0.7 μg/kg/day. The physiologically-based pharmacokinetic/pharmacodynamic-iodide uptake inhibition (PBPK/PD-IUI) model links perchlorate exposure in food and water with perchlorate concentrations in plasma and tissue and resulting NIS inhibition assessed by RAIU studies. The continuum of events in the MOA after NIS inhibition would include possible changes in serum thyroid hormone levels, which have been linked with neurodevelopmental changes in iodine-deficient individuals during early life stages as discussed in the previous section. Using the MOA framework, the model provides a key tool for assessing the potential for the upstream step (iodide uptake inhibition) at different lifestages or in sensitive populations. This MOA framework allows determination of the MCLG using the percent IUI as a surrogate for the adverse effect.

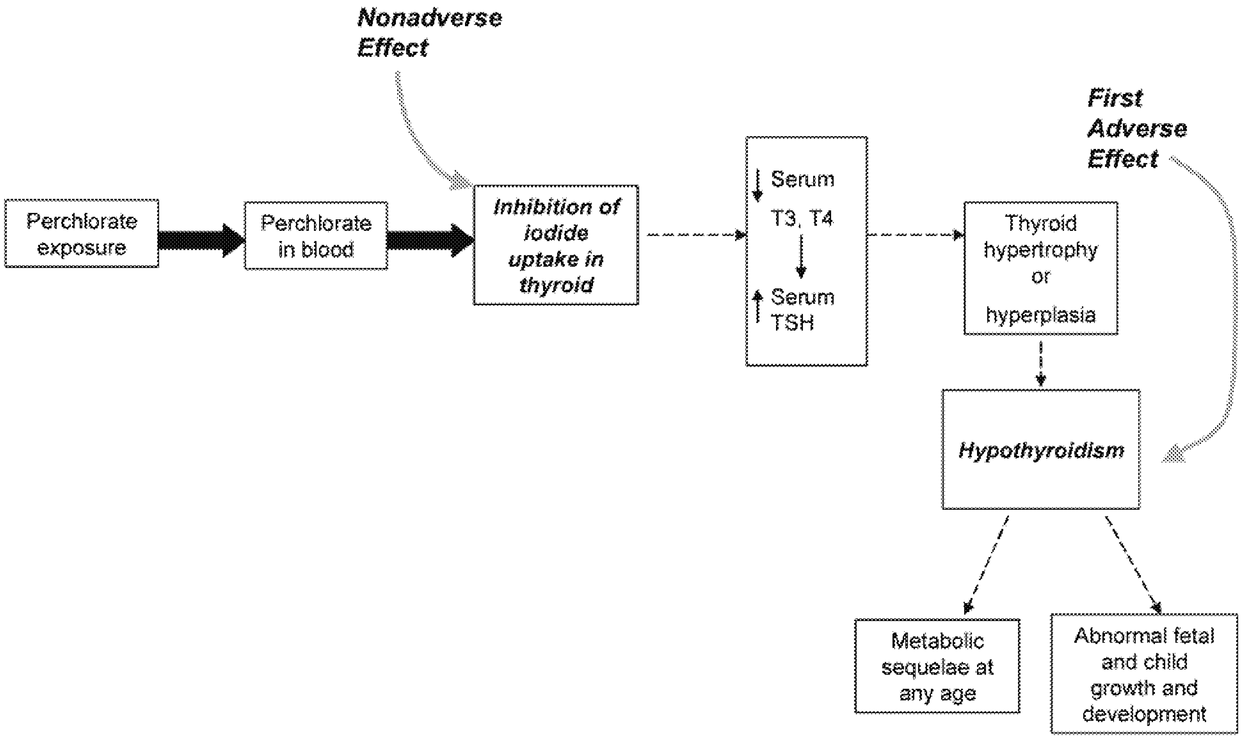

Figure 1. NRC suggested mode of action for perchlorate toxicity in humans indicating the first adverse effect in the continuum. (Reprinted with permission from Health Implication of Perchlorate Ingestion, 2005 by the NAS. Courtesy National Academy Press.)

Research scientists at the toxicology laboratory at Wright-Patterson Air Force Base developed a series of physiological models to describe the effect of perchlorate on the inhibition of thyroidal uptake of radiotracer iodide (Fisher et al. 2000; Clewell et al. 2003a, 2003b; Merrill et al. 2003, 2005). These models included the adult rat, pregnant rat and fetus, the lactating rat and rat pup, and the adult human. The PBPK/PD-IUI models described the uptake, distribution and urinary elimination of both perchlorate and radiotracer iodide anions. Serum levels of perchlorate and radiotracer iodide are predicted to describe active transport of perchlorate and radiotracer iodide into cells expressing the NIS protein, such as the thyroid gland, small intestine, placenta, and lactating mammary tissue (Merrill et al. 2005). Both anions—perchlorate and iodide—compete for active uptake by NIS-expressing tissues. The inhibition of thyroidal uptake of radiotracer iodide by perchlorate is recognized as the primary mode of action for perchlorate leading to potential disruption of the hypothalamic-pituitary-thyroid (HPT) axis by depleting the thyroid gland of iodide used in synthesizing thyroid hormones. RAIU inhibition for the thyroid gland is measured for different doses of perchlorate. Later the PBPK/PD-IUI human model for perchlorate and radiotracer iodide was extended to human life stages (Clewell et al. 2007) to make RAIU inhibition predictions in the sensitive life stages (i.e., the fetus, infant and child). The human PBPK/PD-IUI life stage model (U.S. EPA 2008) was the subject of an EPA-sponsored peer review and underwent modest revisions in response to the reviewers' comments (U.S. EPA 2009). This peer-reviewed model was used for the predictions of RAIU inhibition presented in the EPA white paper (2012) provided to the SAB. This modeling approach starts to answer questions about sensitivity of life stages to RAIU inhibition that otherwise are only qualitative justifications for the UF of 10 used in the RfD to protect sensitive populations.

Future mathematical modeling development should describe HPT axis events after RAIU inhibition in human life stages. The model would need to describe a range of status for thyroid hormones (e.g., hypothyroxinemia), with consideration of the appropriate reference ranges during different lifestages (e.g., trimesters of pregnancy), and recognition of variations among measurement assays for thyroid hormones. An expanded model should describe dietary iodide intake that is the source of iodide for thyroid hormone synthesis; the current model does not describe thyroid hormone levels or the dietary iodide intake. Expansion of the model to incorporate these aspects has been accomplished in the adult rat (McLanahan et al. 2008, 2009) and ongoing efforts to model humans were reported for the pregnant mother and fetus (Lumen et al. 2013).

Lumen and coworkers described the serum pharmacokinetics of perchlorate and dietary iodide in the near-term pregnant mother and fetus, thyroid iodide stores, iodide, and total serum T4 (from which fT4 is calculated) and total T3. The competitive inhibition of each anion (perchlorate and dietary iodide) on the other for uptake by the NIS is described for the thyroid gland and placenta. Serum fT4 levels in the mother and fetus were predicted at steady state for a range of dietary iodide intakes ranging from mild iodide deficiency (75 μg/day) to sufficient iodide intake (250 μg/day) with no perchlorate intake (exposure) and for a range of perchlorate intakes (0.00001 to 1.0 mg/kg/d). The authors predicted the exposure conditions for perchlorate, under varying dietary iodide diets, that would result in serum maternal fT4 levels associated with hypothyroxinemia (decrease in serum T4 and changes in serum TSH within normal reference ranges) and for the onset of hypothyroidism (increase in serum TSH and decrease in serum fT4 levels). This biologically based dose response (BBDR) model for the HPT axis in the pregnant woman and fetus provides a quantitative approach to better understand the adverse health consequences (hypothyroxinemia and hypothyroidism) using an MOA-based analysis of perchlorate exposure for a range of dietary iodide intakes. A substantial enhancement in this modeling effort reported by Lumen et al. (2013) would be to perform Monte Carlo analysis to address variability in the human population. The contributions to NIS inhibition from other NIS inhibitors (e.g., thiocyanate, nitrate) could also be incorporated in the modeling, but may be addressed as qualitative uncertainties at this time.

Documenting the MOA framework and the PBPK/PD-IUI model to make them accessible to both modelers and non-modelers will be an important challenge for the EPA. By comparison with the simple algebraic default equation describing an MCLG as a function of a few terms (e.g., RfD, body weight, water intake, and source contribution), the proposed analysis could appear opaque despite the fact that it captures detailed scientific information. The model documentation should describe model structure, data used to establish that structure and to estimate parameter values, sensitivity of model outputs such as NIS inhibition to parameters, and characterization of the model strengths and limitations. Publications on model evaluation and documentation (Clark et al. 2004; Chiu et al. 2007; Thompson et al. 2008) and the World Health Organization International Programme on Chemical Safety PBPK Guidance (WHO 2010) provide useful approaches for developing documentation. This documentation should also reference the published literature on the model and the 2009 peer review of the 2008 EPA PBPK/PD-IUI model and its subsequent revisions.

Recommendations:
The SAB recommends that the EPA utilize an MOA framework for developing the MCLG that links the different steps in the proposed mechanism from perchlorate exposure through NIS inhibition to thyroid hormone changes and finally to neurodevelopmental impacts. Within this MOA framework, the PBPK/PD-IUI model provides a tool for integrating exposure (e.g., different drinking water consumption rates) with the biological changes occurring at the different lifestages to obtain predictions

for perchlorate pharmacokinetics and resulting symporter inhibition to address these initial steps of the MOA framework. (See section 3.4.1)

The EPA should extend the PBPK/PD-IUI model expeditiously to describe changes in thyroid hormone levels. This would provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages.

Development of a clear communications strategy, including documentation of the MOA framework and the PBPK/PD-IUI model, will facilitate stakeholder and public understanding of the approach used to develop the MCLG.

3.2.2. Strengths and Limitations of EPA's PBPK Model Results

Charge Question:
What are the strengths and limitations of the two PBPK model results described in this effort?

The two analyses that the EPA presented in the white paper address different aspects of the model and its use in developing an MCLG (U.S. EPA 2012). The first analysis (Table A3 in the EPA white paper) evaluates the predicted RAIU inhibition for the same perchlorate dose (7 μg/kg/day) that arises from biological variations captured in the PBPK model for different lifestages. This analysis helps support the use of the UF in deriving the RfD as it predicts greater inhibition at fetal and neonatal/infant lifestages as compared to the adult. The second analysis (Table A4 in the EPA white paper (2012)) evaluates the combined effects of life stage-dependent differences in exposure (e.g., drinking water consumption) with the biological variability by assessing the predicted RAIU inhibition at fixed drinking water exposure concentrations.

The SAB identified some strengths and limitations of the first analysis of life stage-dependent biological variability. A limitation of the first analysis is the selection of the urinary excretion rate for perchlorate. Literature for iodide excretion indicates the rate is faster in neonate/infants than at later ages, which might then be expected to be the case for perchlorate (Malvaux et al. 1965; Oddie et al. 1966; Ponchon et al. 1966). The values in the model need to be reassessed and justified. While the model addresses life stage variations, it is a model of the average human at each life stage. Extension of the model to a full population description would be useful, but it is recognized that this would be a major effort. In the absence of a full population analysis, it is important for the EPA to document and justify when model parameter values are selected that either represent an upper or lower bound rather than the average (e.g., using upper bound drinking water intake) or, when given uncertainty in the experimental literature, they select a specific value (e.g., the highest or lowest urinary clearance rate) rather than using an average value. Sensitivity analyses for PBPK model predictions could be useful for identifying key parameters to make such population analyses more tractable or to evaluate and demonstrate the impact of selection of particular parameter values. The human biological modeling uses life stage-specific uptake rates mediated by NIS levels but does not reflect changes in NIS in response to TSH regulation, if they occur; the model does not currently include thyroid hormones to permit such a feedback description nor potential effects of chronic perchlorate exposure. A strength of the analysis is that the EPA evaluated the model's capability to describe both perchlorate transport into breast milk and assessed the expected impact of NIS inhibition on iodide transfer to breast milk, so that predictions for inhibition in breast-fed infants account for both these aspects.

The second analysis would share these same strengths and limitations because it combines the biological variability with life stage-dependent differences in exposures. Data for water and diet consumption at the different lifestages that inform the exposure modeling appear somewhat variable in extent across the lifestages.

The major strength and limitation of the current model as noted above is that it provides a tool to link perchlorate exposure with impacts on iodide uptake, but goes no further in the MOA at this time. Nevertheless, this early step can usefully be extended to represent the consequences of those changes on thyroid hormone levels at different life stages under varied conditions of basal iodide intake and thyroid hormone status.

Recommendation:

The SAB finds the second analysis is the more valuable for asking what extent of NIS inhibition would be predicted for different potential MCLG concentrations; the analysis provides perspective on the protection offered by different perchlorate concentrations. Since it uses 90th percentile drinking water consumption rates, it starts to address population issues in exposure, although most of the biological aspects of the model are for an average individual. As noted above, the EPA needs to document and justify when selecting values other than average values in the absence of a full population analysis in order to be transparent about scientific, science policy or regulatory policy choices involved.

Limited data have been available for perchlorate in plasma and breast milk so checking the availability of new data in the literature would inform alternative parameterization or characterization of the uncertainty in the current model parameters. There is widespread sensitivity to information on potential impacts of breast and bottle-feeding for infants, so care in communications about these topics will be beneficial.

The choices for urinary clearance values for perchlorate and iodide at the different life stages should be reviewed and the current or revised values documented and justified as appropriate for a model of the average individual at each life stage in light of uncertainties in the scientific literature.

3.3. Epidemiological Studies

Charge Question: How should EPA consider the post-NRC epidemiology data in deriving an MCLG?

The SAB finds that the epidemiological data published since the NRC 2005 report are useful for estimating the size of potentially sensitive populations in the United States, estimating the extent to which the United States general population and sensitive populations are exposed to perchlorate and other goitrogens, and estimating the relative source contribution of perchlorate in drinking water among sensitive populations not included in the Food and Drug Administration (FDA) Total Diet Study (Murray et al. 2008).

The SAB concludes that these epidemiological data are insufficient to guide causal inference of an association between perchlorate exposure and thyroid dysfunction in pregnant women, neonates or the general population. Limitations concerning study design, exposure assessment, sample size, and statistical modeling have resulted in inconsistent findings. The current body of epidemiologic evidence cannot provide validation of a safe level of perchlorate in drinking water.

The SAB provides specific comments on how the agency could use the exposure and biomonitoring studies published since the NRC report (2005). The SAB identifies research components that the EPA and others should consider when planning analyses based on existing data or when developing new studies to improve the agency's understanding of the effect of perchlorate exposure in hypothyroxinemic women. The SAB also provides specific comments in Appendix B on the strengths and weaknesses of recent epidemiologic studies identified by EPA and others.

3.3.1. Using Exposure and Biomonitoring Studies

Manuscripts published since the 2005 NRC report are informative for providing an estimate of the size of potentially sensitive populations in the United States, for estimating exposure to perchlorate and other goitrogens among sensitive populations and for estimating the relative source contribution of perchlorate in drinking water among sensitive populations.

Prevalence of Sensitive Populations

Epidemiologic studies can be used to identify sensitive populations. However, methodological considerations (see review of epidemiologic literature in Appendix B) limit the scientific conclusions that can be drawn from the studies published to date. The National Health and Nutrition Examination Survey (NHANES) is a cross-sectional, population-based survey that over-sampled some subgroups to produce a relatively representative sample of the U.S. population (CDC 2004). NHANES can be used to estimate the prevalence of potentially sensitive populations, including pregnant women who are iodide insufficient.

Iodide is critical for the formation of thyroid hormone. Iodide deficiency occurs when iodide falls below recommended levels. According to the WHO guidelines, urinary iodine levels > 100 µg/L (representing an iodine daily intake of 150 µg) are considered "adequate" among the general population (WHO 2001). However, among pregnant women the demand for iodine is greater; therefore, in this population group, urinary iodine levels <150 µg/L are considered "insufficient" (Andersson et al. 2007). Caldwell et al. (2005) used iodine measured in spot urine samples from NHANES 2001-2002 to characterize iodine levels in the U.S. population. Among women ages 15 to 44, 37.2% have iodine levels <100 µg/L. Using the 2005-2006 and 2007-2008 NHANES samples, Caldwell et al. (2011) reported that the proportion of women ages 15 to 44 with urinary iodine <100 µg/L remains relatively constant at 38.1%. Among pregnant women, however, 56.7% have urinary iodine concentrations less than the recommended 150 µg/L.

Estimating Perchlorate Exposure and Exposure to Other Goitrogens

Biomonitoring and exposure studies published since the 2005 NRC report can be used to identify subgroups with the highest exposures to perchlorate. NHANES studies can produce population estimates of perchlorate exposure, including among potentially sensitive subgroups.

Blount et al. (2006) provide information for estimating perchlorate exposure using spot urine samples among a representative sample (n=2820) of males and females ≥ 6 years of age in NHANES 2001-2002. Perchlorate was detectable in all samples, indicating widespread exposure. Children ages 6 to 11 years had the highest concentrations of urinary perchlorate (geometric mean: 5.40 µg/L, adjusted for race/ethnicity, sex, age, fasting time and urinary creatinine).

Huber et al. (2010) provides information for estimating perchlorate exposure in pregnant women. The authors used data from a random subset of NHANES 2001-2002 that measured perchlorate in n=2708 spot urine samples (creatinine adjusted), including 116 pregnant women. Compared to non-pregnant women aged 15 to 44 years, pregnant women had significantly higher average daily perchlorate intake (geometric mean: 0.060 µgkg/day vs. 0.051 µgkg/day). These data, however, may be imprecise because they are estimated from a single spot urine sample (Mendez et al. 2010) and because during pregnancy, creatinine adjustment for urinary dilution is less effective as pregnancy alters creatinine excretion (Blackburn 2007). Huber et al. (2010) also examined the EPA Unregulated Contaminant Monitoring Regulation (UCMR) data, which provide data on perchlorate levels in public drinking water sources. In the UCMR data, the estimated perchlorate contribution from food was 86% and from drinking water was 14%.

Some potentially sensitive populations, such as infants, are not represented in NHANES. Exposure information for these missing subgroups can be inferred from exposure and biomonitoring studies that specifically targeted these groups. While these studies are often comprised of highly selected study subjects and may not be representative of the U.S. population, the paucity of epidemiologic data on potentially sensitive populations makes these targeted studies useful nevertheless. Some of the studies published since the NRC report may inform parameters for PBPK/PD models.

Four studies provide information for estimating perchlorate exposure among infants less than 6 months of age (Kirk et al. 2005; Dasgupta et al. 2008; Schier et al. 2010; Valentin-Blasini et al. 2011). Kirk et al. (2005) reported average perchlorate concentrations of 2.0 μg/L (range: 0.0 to 11.0 μg/L) and 10.5 μg/L (range: 1.4 to 92.2 μg/L) in 47 samples of dairy milk from 11 states and 36 breast milk samples from lactating volunteers in 18 states, respectively. Using these data, the authors estimate that the majority of breast-fed infants would exceed the NRC RfD (0.7 μg kg/day). Dasgupta et al. (2008) measured perchlorate in repeated milk and urine samples from a small number of lactating women (n=13). Based on these data, the authors estimated that 9 of 13 infants exceeded the NRC perchlorate RfD. Schier et al. (2010) estimated perchlorate intake from four varieties of infant formula: bovine-based with lactose, bovine-based without lactose, soy-based, and elemental. The authors reported that bovine formula with lactose had the highest concentrations of perchlorate (geometric mean: 1.72 μg/L), which could lead to estimated daily doses at 1 and 6 months of age that exceeded the perchlorate RfD. Valentin-Blasini et al. (2011) directly measured perchlorate exposure in the urine of breast- and formula-fed infants age 1 to 377 days by collecting up to four samples per infant (n=205 samples from 92 infants). The highest average perchlorate concentrations were among breast-fed infants (geometric mean: 2.65 μg/L vs. 1.3 μg/L for bovine-based formula and 0.35 μg/L for soy-based formula). Correspondingly, the highest average estimated perchlorate intake (geometric means for breast-fed, bovine-based formula fed, and soy-based formula fed, respectively: 0.922 μgkg/day, 0.103 μgkg/day, and 0.027 μgkg/day) were among breastfed infants. Based on these estimates, 16% of all infants (and 31% of breast-fed infants) had at least one feeding with perchlorate exposure exceeding the RfD. There was, however, a great deal of intra-individual variability of perchlorate concentrations across repeated samples (intraclass correlation coefficient (ICC) = 0.07). These authors also reported concurrent urinary levels of nitrate, thiocyanate, and iodide concentrations.

In addition to perchlorate, NHANES provides an opportunity to evaluate the extent to which the U.S. population, including sensitive populations, may be co-exposed to other goitrogens with comparable MOAs, such as thiocyanate and nitrate. The ion chromatography coupled with tandem mass spectrometry method used to measure perchlorate in urine in the NHANES sample from 2001-2002 provides simultaneous measurement of nitrate, thiocyanate and iodide (Valentin-Blasini et al. 2007). While the geometric mean concentrations of all four compounds are reported in Blount et al. (2006) and Mendez and Eftim (2012), these data have not yet been described in detail in a peer-reviewed publication (English et al. 2011). Ultimately, while data from epidemiologic studies are insufficient for evaluating the causal association between perchlorate exposure and thyroid dysfunction because of the methodological issues described in Appendix B, these studies may be useful for understanding perchlorate exposure and co-exposure to other goitrogens among pregnant women and infants.

Estimating the relative source contribution

The relative source contribution (RSC) is the proportion of an individual's daily perchlorate reference dose remaining for drinking water after considering exposure from other sources. For perchlorate, food is the only other important exposure pathway. The EPA used the FDA Total Diet Study by Murray et al. (2008) to estimate the drinking water RSC (Table A-2, U.S. EPA 2012) based on estimated perchlorate intake from food among 14 age/sex subgroups of the U.S. population. RSC estimates ranged from 44% to 89%, although the Total Diet Study did not provide intake estimates for all potentially sensitive populations (e.g., pregnant or lactating women, infants less than 6 months of age). Studies outlined above provide information for estimating perchlorate dose for drinking water and food intake levels within sensitive subgroups.

3.3.2. Epidemiologic Studies of Associations between Perchlorate Exposure and Thyroid Dysfunction

The SAB finds that epidemiologic studies published since the 2005 NRC report are insufficient to guide causal inference concerning an association between perchlorate exposure and thyroid dysfunction, or to support a derived MCLG. Methodological and statistical issues limiting the applicability of these studies to the Charge question include: (1) use of ecological measures of perchlorate exposure based on community drinking water concentrations; (2) cross-sectional study designs; (3) small sample size; (4) misspecified statistical models that do not properly assess confounding and effect measure modification or explore potential non-linear associations; and (5) inconsistent treatment of creatinine, iodide status, thyroid antibodies and co-exposures to other goitrogens. These issues are discussed in detail in Appendix B.

3.3.3. Recommendations for Future Analyses and Studies

Existing exposure and biomonitoring studies are useful for understanding the prevalence of sensitive populations. Additional analyses of NHANES data can be undertaken to estimate the prevalence of sensitive populations not previously described. The typically small number of pregnant women in NHANES, however, may limit the precision of these analyses. In addition to perchlorate, urinary concentrations of other goitrogens are also available in NHANES data.

It may be possible to pool data from existing studies with similar design and analytic measures to alleviate some of the methodological and statistical issues discussed in Appendix B. However, *post-hoc* pooled analyses should be undertaken with caution and with careful consideration of potential sources of heterogeneity across studies.

Recommendations:

Prospective studies of individual urinary biomarkers of perchlorate exposure and thyroid function and child neurobehavioral development are recommended. Studies that evaluate hypothyroxinemia endpoints during pregnancy may offer a better picture of the role of perchlorate as a contributor to meaningful health outcomes in susceptible populations, specifically endpoints directly related to neurodevelopment.

Additionally, future studies may benefit from improved statistical methods. Investigating non-linear patterns of effect across low, moderate and high exposure categories may be informative for identifying potential associations at the extremes of the exposure distribution. Careful and thorough consideration of appropriate control variables may reduce bias and improve the precision of estimated perchlorate effects. For instance, directed acyclic graphs (DAGs) are useful tools that apply systematic rules to graphically depict assumptions about causal relations among variables (Greenland et al. 1999). DAGs can inform statistical modeling strategies by helping to determine which covariates should be controlled to reduce confounding and avoid bias. Rather than adjusting models for characteristics of potentially vulnerable populations, it may be more informative to stratify the analysis by the characteristic. For instance, iodide-deficient pregnant women may be more susceptible to the effect of perchlorate than iodide-sufficient pregnant women. Stratification highlights this differential susceptibility instead of providing an average effect over all iodide levels. Such studies, however, would require large sample sizes to observe these divergent effects.

Finally, co-exposures to other goitrogens should be consistently measured in future studies and consideration should be given to conducting sensitivity analyses to address uncertainties of modeling co-exposures to compounds with the same (or different) modes of action. Studies of the temporal variability of perchlorate, iodide, nitrate, and thiocyanate in spot urine samples also should inform methods for minimizing measurement error.

3.4. Integration of Information

3.4.1. Integrating Information to Derive a MCLG

Charge Question:
How can EPA best use the total body of information to derive a health protective MCLG, while considering the results of epidemiology and biomonitoring data in establishing bounds on potential values?

The EPA white paper describes a process for deriving an MCLG for perchlorate that incorporates an RfD and RSC (U.S. EPA 2012). The SAB recommends that the EPA integrate the available information on perchlorate to derive an MCLG using the MOA previously identified for perchlorate rather than the default algebraic approach. The MOA approach relies on the use of a PBPK/PD model that relates perchlorate intake via drinking water with percent IUI. The SAB recommends that EPA use a PBPK/PD- IUI approach and where possible expand this approach to relate the percent IUI with thyroid hormone perturbations and potential adverse neurodevelopmental outcomes.

The SAB recommendation represents an important and novel opportunity that should be implemented carefully with attention to data quality and methodological rigor. At each step, the EPA should critically evaluate available data and describe the strengths and limitations. The SAB concludes that a stepwise "integrated" approach is a logical way forward allowing multiple sources of information to be integrated into the MCLG derivation. The SAB recommends that the EPA undertake the necessary literature review and critical analysis to fully test the feasibility and utility of the approach. Further, the SAB recommends that the EPA incorporate into the MCLG development the recent recommendations from the National Academy of Sciences to improve the scientific basis and clarity of assessment documents (NRC 2009, 2011).

This SAB advisory report presents specific recommendations for considering sensitive life stages, PBPK-PD modeling, and the epidemiological and biomonitoring data that were presented to the SAB to derive an MCLG. While the charge to the SAB focused on scientific literature published since the release of NRC's 2005 report, clearly the agency needs to consider the entire literature related to ingestion of perchlorate, pharmacokinetics of perchlorate and the effects (dynamics) of perchlorate (such as Clewell et al. 2001, 2003a, 2003b). In addition, the SAB recommends that EPA should also consider available data on potential adverse health effects (neurodevelopmental outcomes) due to thyroid hormone level perturbations regardless of the cause of those perturbations.

The three previous sections provide the foundation for an approach to derive the MCLG for perchlorate using the entire body of available information.

- *Sensitive Life Stages*: The most important SAB recommendations are the focus on *subtle* changes in thyroid hormone levels. The SAB finds the most sensitive life stages are the fetuses, neonates and infants because these are the stages when thyroid-dependent brain development occurs. The development of the MCLG must consider the perchlorate exposure pathways relevant to each of these sensitive life stages, which for fetuses and breastfed infants includes exposure of pregnant and lactating women, respectively. Thus, the sensitive populations that the EPA should consider for exposure to perchlorate are the fetuses of hypothyroxinemic pregnant women and infants exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women. This delineation of sensitive subpopulations would replace "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" as defined by the NRC (2005).

- *PBPK/PD Modeling:* The current PBPK/PD-IUI model can link perchlorate exposure in food and water with perchlorate concentrations in plasma and tissue and resulting NIS inhibition assessed by RAIU studies. The continuum of events in the MOA after NIS inhibition would include possible changes in serum thyroid hormone levels, which have been associated with neurodevelopmental changes in offspring of iodine-deficient women. Work to extend the PBPK/PD-IUI model with links to serum thyroid hormone levels is presented in Lumen et al. (2013).

- *Epidemiology and Biomonitoring Data:* The SAB concluded that the data in the scientific literature since the 2005 NRC report were insufficient to provide the basis for an MCLG. However, a consideration of the full literature and/or other combined analyses (such as meta-analysis or pooled analysis) might provide important information that could be used to support an MCLG based on hypothyroxinemic pregnant and lactating women, their fetuses and infants, and bottle fed infants as the sensitive subpopulation.

The SAB recognizes that an MOA has been determined that links the different steps in the proposed mechanism leading from perchlorate exposure through NIS inhibition to thyroid hormone changes and finally neurodevelopmental impacts. The SAB finds that this framework provides a strong foundation for the EPA to develop the MCLG. Within this MOA framework, the PBPK/PD-IUI model provides a tool for integrating exposure (e.g., different drinking water consumption rates) with the biological changes occurring at the different lifestages to obtain predictions for perchlorate pharmacokinetics and resulting NIS inhibition to address these initial steps of the MOA framework.

In order to ensure that the model is predictive of actual adverse health outcomes, the EPA will need to examine the literature on the associations between reduced iodide uptake, subtle changes in thyroid hormone levels as defined by hypothyroxinemia, and adverse neurodevelopmental outcomes in children, including literature not specifically designed to include perchlorate (i.e., iodide deficiency, thyroid hormone levels, hypothyroxinemia).

The SAB recognizes the existence of a large amount of scientific research on perchlorate and also thyroid hormone perturbations and potential adverse health outcomes (unrelated specifically to perchlorate). As a result, the SAB recommends that the EPA explore the use of the literature beyond that which focuses solely on perchlorate.

The SAB notes that the recommendation to use the MOA and PBPK/PD mathematical model is a novel and alternative approach to developing the MCLG. The SAB emphasizes the need for transparency in approaches for identifying and/or excluding model input data, compiling datasets for purposes of identifying and bounding numerical estimates needed for the MCLG and transparency and robust explanation of the approach and modeling used for the derivation of the MCLG.

Regarding using epidemiological and biomonitoring data to establish the bounds on a potential MCLG of perchlorate, the SAB was not provided the full extent of data on the epidemiologic, biomonitoring, water concentration, or physiologic data related to perchlorate, nor asked to complete each step in the new approach to developing an MCLG. Therefore, the SAB finds that it is premature to provide specific guidance on bounding estimates. The SAB recommends that the EPA fully evaluate the breadth and depth of the data, data variability and uncertainty, and the utility of the data. The SAB further notes the importance of incorporating metrics and statistics, such as 95th percentiles and ranges of values rather than point estimates representing average population values (see Section 3.2).

The SAB notes that in applying the framework to the epidemiological data, the agency should consider the available evaluation tools such as Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklists (ISPM 2012) or Grading of Recommendations Assessment, Development and Evaluation (GRADE 2012). The SAB recommends that as the EPA integrates information, the agency should consider the general frameworks for evaluating quality of studies used to support the MCLG derivation (as discussed briefly in Appendix C).

Steps In A Mode of Action Modeling Approach

The SAB recommends the following MOA-based approach for using PBPK/PD modeling and additional clinical and toxicological data to inform the derivation of a health-protective MCLG recognizing that the sensitive populations for perchlorate exposure are the fetuses of hypothyroxinemic pregnant women, and infants exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women. The effects of concern are neurodevelopmental outcomes in the offspring. The SAB presents this approach as a series of steps to progressively improve the scientific rigor in the evaluation of different life stages considered for the MCLG and recognizes that the steps described here may require an increased level of effort and additional data. As part of this approach, the EPA would obtain a point of departure (POD) from which the MCLG would then be derived. The POD selection would be dependent upon the MOA-based endpoint used in EPA's analysis (e.g., NIS inhibition, thyroid hormone changes, neurodevelopmental effects). The approach is discussed below and summarized in Figure 2. The SAB's recommended approach follows the solid arrows in the diagram and an alternative approach follows the dashed arrows in the figure. As shown, there are three proposed approaches (2, 3a, or 3b) available to the agency that vary in terms of data, resource, and time requirements.

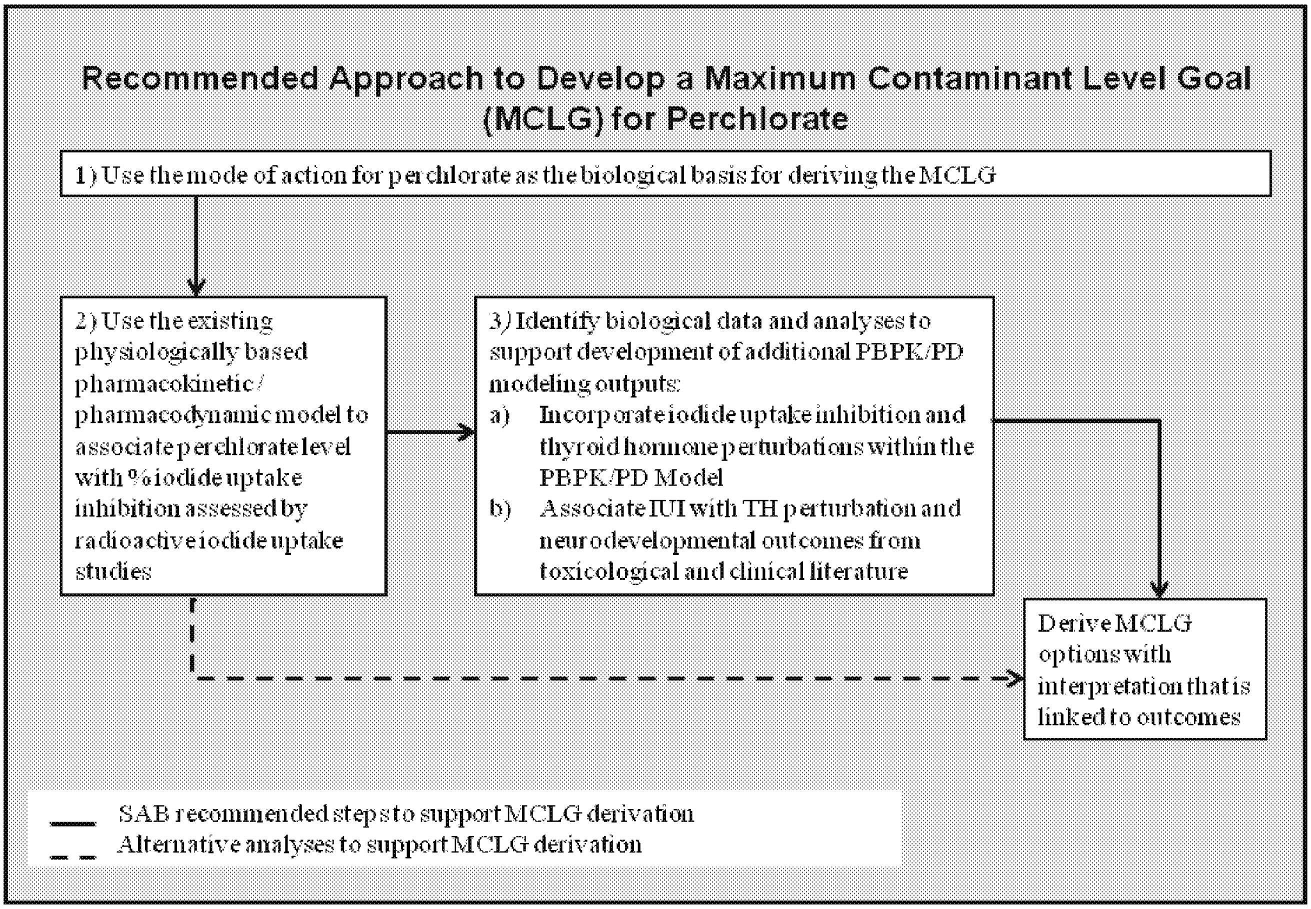

Figure 2. Steps in a mode of action and modeling approach to derive an MCLG for perchlorate.

Step 1.Use the MOA for perchlorate (See Figure 1, Section 3.2.) as the biological basis for deriving the MCLG. This MOA links perchlorate exposure to NIS inhibition to thyroid hormone changes and neurodevelopmental impacts.

Step 2. Use the existing PBPK/PD-IUI model to link perchlorate exposure from drinking water with perchlorate concentrations in plasma and tissue and resulting NIS inhibition assessed by RAIU studies. The model in its current form addresses important aspects of biological life stage sensitivities, but limitations should be clearly stated or the model should be adjusted (e.g., iodide and perchlorate clearance in the early postnatal period as noted in Section 3.2). While the preferred MOA approach would link IUI with subsequent events (e.g., thyroid hormone perturbations), using predictions of IUI from the current PBPK/PD-IUI model is consistent with the derivation of the RfD. This would be the most rapid analysis for EPA to implement since the model predicts percent IUI for the relevant life stages and has already been subject to peer review. The NRC report proposed that by minimizing IUI, one would minimize subsequent events and adverse health consequences. The limitation of using either the RfD in the default algebraic equation or IUI predicted by the model is that both describe a precursor event and neither explicitly provides predictions for subsequent events and adverse outcomes. The advantage of the PBPK/PD-IUI model approach over the algebraic calculation is that it explicitly predicts IUI at the relevant lifestages that the SAB considers important.

Step 3. The SAB urges the EPA to expand the PBPK/PD model to address as many of the downstream MOA outcomes as possible. The agency should identify literature and conduct analyses to support the model outputs for the downstream steps. While incorporating these subsequent steps into the PBPK/PD-IUI model is the preferred approach, the SAB recognizes the additional effort required. An interim approach is to obtain data from the clinical and toxicological literature to describe empirical relationships to the downstream effects not provided by the model outputs. Benefits and limitations to both approaches are described below.

a) The SAB recommends that the EPA extend the PBPK/PD-IUI model to incorporate predictions of thyroid hormone perturbations. Such an extension of the model would need to explicitly address dietary iodide intake (both adequate and insufficient intake) and thyroid hormone production at different life stages for women and children with adequate and insufficient iodide intakes. This approach would permit assessment of the predicted exposure-response relationship for perchlorate exposure and alterations in thyroid hormone levels (e.g., decreases in serum fT4). To establish what magnitude of decrease in T4 would be relevant and establish a point of departure, EPA would need to document the relationship between the levels of maternal serum biomarkers, (e.g., fT4 and TSH) associated with adverse effects on neurodevelopment of infants. Examples of useful literature to support this step may include the Haddow et al. (1999) and Pop et al. (1999) studies. The assumption of this approach is that regardless of the cause of decreased iodide for thyroid hormone synthesis (e.g., lack of dietary intake or competition by perchlorate) the subsequent events are driven by the decrease of thyroid hormone levels. Such an effort will require resources and time, likely up to a couple of years. The SAB notes that similar modeling efforts are underway at other federal agencies and collaboration with these researchers could facilitate development thereby reducing the level of effort.

b) An interim approach is to use the existing PBPK/PD-IUI model to estimate IUI and then develop empirical relationships for each of the steps beyond perchlorate-mediated IUI. The thyroid clinical literature would be used to identify the degree of symporter inhibition (percentage IUI) required for onset of hypothyroxinemia in the pregnant woman. The relevant literature for this step may include the clinical literature on iodine deficiency as well as other literature on hypothyroxinemia (see section 3.1). If one could establish equivalence between perchlorate-mediated IUI and reduced iodide intake as observed by measured urinary iodide, one could utilize the relationship between urinary iodide and thyroid hormones levels described in Silva and Silva (1981) for varying levels of iodide intake in pregnant women. Again, the relationship between changes in thyroid hormone levels and neurodevelopmental outcomes just discussed would be required to complete the linkages. This approach will require resources and time, perhaps less than required for explicitly expanding the PBPK/PD-IUI model to include thyroid hormone levels, but that depends upon being able to identify data to provide the needed empirical relationships for steps between IUI and neurodevelopment.

As a check on the predictions from either of these approaches, the agency could compare model predictions with epidemiological data. As previously discussed, the post-2005 epidemiological studies have significant limitations for the purposes of MCLG derivation and have limited utility for evaluating the PBPK/PD-IUI model outputs. However, it may be possible to gain a better understanding of the effect of perchlorate exposure on thyroid hormone perturbations from an examination of the raw data, i.e., a pooled analysis. If a pooled analysis is pursued, the SAB advises exploring the recent Pearce et al. (2010, 2011, and 2012) studies as one potential data source given the common set of investigators. A pooled analysis, however, addresses only some of the existing limitations and would still require cautious interpretation regarding causal inference because these data are cross-sectional.

Pooled analyses are challenging and the data to be combined must be carefully evaluated to ensure that such an analysis is appropriate. Methodological issues particular to pooled analysis of biomarkers studies are presented by Taioli and Bonassi (2002). The improved statistical methods described in the recommendations under Section 3.3.3 also would be relevant for any pooled analyses. (Further information on model misspecification in the epidemiological literature the SAB reviewed is found in Appendix B).

The SAB identified a number of potential options to identify and apply biological data in support of the PBPK/PD-IUI modeling to derive an MCLG for perchlorate. The SAB provides rough estimates of the time requirements for each potential option below.

Short-term option (estimated up to one year)

- Use existing clinical literature to identify empirical linkages between existing PBPK/PD-IUI model to downstream changes (i.e., thyroid hormones, neurodevelopment)

Medium-term option (estimated one to two years)

- Extend PBPK/PD-IUI model to incorporate the prediction of thyroid hormone perturbations

Long-term options (estimated more than two years)

- Pooled analysis of existing epidemiological data
- New longitudinal epidemiological studies

This MOA-based approach is consistent in some ways with the concept of Adverse Outcome Pathways that is being used increasingly by the agency to understand and describe the linkages between initiating molecular events and adverse outcomes. Going forward, the agency should consider whether it would be beneficial to present perchlorate and the PBPK/PD-IUI modeling in the context of an adverse outcome pathways framework.

3.4.2. Estimating Reductions In Adverse Health Effects

Charge Question:

How can EPA use the available data to estimate reductions in adverse health effects (i.e., dose response) that are likely to result from reducing perchlorate levels in drinking water?

The SAB finds that the epidemiological studies provided to the panel are inadequate for quantitatively estimating reduction in adverse health effects that would result from regulating perchlorate in drinking water. Specifically, the epidemiological studies provided are not adequate to support quantitative dose-response modeling and related adverse health effects reduction analyses. To move toward the goal of quantitative dose-response and reduction in adverse health effects assessment for perchlorate, the agency must first define:

- The adverse effect. The SAB recognizes neurodevelopmental effects arising from exposures during the sensitive lifestages as the potential adverse effects of perchlorate. These effects may range from changes in brain development and structure to impaired behavior, learning and memory, among others (Rovet and Willoughby 2010). These effects have been observed in studies of iodine deficiency or altered thyroid hormone function – conditions consistent with the MOA for perchlorate. Changes in brain development and structure have been observed in studies of animals where maternal hypothyroxinemia or thyroid hormone deficiency were modeled (for example, Lavado-Autric et al. 2000; Auso et al. 2004). Impaired learning, cognition and motor development have been observed in studies of children whose mothers were iodine deficient or hypothyroxinemic (for example, Zoeller and Rovet 2004; Henrichs et al. 2010; Li et al. 2010; Suarez-Rodriguez et al. 2012). For the purposes of deriving an MCLG for perchlorate, the SAB recommends that the EPA focus on measurements relevant to these adverse effects including iodine deficiency and hypothyroxinemia.

- The sensitive population. The sensitive populations for perchlorate exposure are the fetuses of hypothyroxinemic pregnant women and infants exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women. This would replace "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" as defined by the NRC (2005).

As a first step in beginning to understand reductions in adverse health effects, EPA should examine shifts in the distribution of exposure to perchlorate to the sensitive subpopulation if relevant data are available.

Any further effort to gain insight on reductions in adverse health effects depends on the availability of data as EPA proceeds along the steps of the recommended integrated approach, as shown in Figure 2. For example, if EPA can proceed by making empirical linkages of perchlorate levels in water and associated PBPK/PD model output (IUI and TH changes) with neurodevelopmental effects from literature sources (Figure 2, Step 3b), the EPA may have a means to assess how a particular perchlorate level relates to a specific outcome. If the health effects literature contains ranges of IUI or TH and a range of effects are described, the EPA may be able to analyze these three distributions (perchlorate in water, modeled output of IUI and TH, literature on IUI or TH linked to a range of effects) empirically connected in series to support statements about reductions in adverse effects.

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APPENDIX A: Charge to EPA Science Advisory Board

LIFE STAGE CONSIDERATIONS AND INTERPRETATION OF RECENT EPIDEMIOLOGICAL EVIDENCE TO DEVELOP A MAXIMUM CONTAMINANT LEVEL GOAL FOR PERCHLORATE

Background

On February 11, 2011 (U.S. EPA, 2011a), EPA published a determination to regulate perchlorate under the Safe Drinking Water Act (SDWA) because:

- perchlorate may have an adverse effect on the health of persons;
- perchlorate is known to occur or there is a substantial likelihood that it will occur in public water systems with a frequency and at levels of public health concern; and,
- in the sole judgment of the Administrator, regulation of perchlorate presents a meaningful opportunity for health risk reduction for persons served by public water systems.

EPA has initiated the process to develop a Maximum Contaminant Level Goal (MCLG) and National Primary Drinking Water Regulation (NPDWR) for perchlorate. The MCLG is a non-enforceable goal defined under the SDWA (§1412.b.4.B) as *"the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."* For perchlorate, the NPDWR will likely specify an enforceable Maximum Contaminant Level (MCL) and monitoring and reporting requirements for public water systems. The SDWA (§1412.b.4.B and D) specifies that the enforceable MCL be set as close to the MCLG as feasible using the best available technology, treatment techniques, and other means (taking cost into consideration).

The regulatory schedule established by SDWA requires EPA to publish a proposed MCLG and NPDWR within 24 months of making a determination to regulate a contaminant and promulgate a final regulation within 18 months of the proposal. As part of this proposed rulemaking, EPA also must develop a Health Risk Reduction and Cost Analysis that includes an assessment of the quantifiable and non-quantifiable health risk reduction benefits likely to occur as a result of treatment to remove the perchlorate. SDWA further requires that when proposing any NPDWR that includes an MCL, the Administrator must analyze "*[t]he effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population*[6]."

[6]*SDWA uses the term subpopulation to refer to groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other groups that can be identified and characterized and are likely to experience elevated health risks. In 2005 EPA started using the term life stages to refer* to age-defined groups. All life stages are subpopulations but not all subpopulations are life stages. In this document, the term life stage is used predominantly because of the focus on infants and very young children.

In 2005, at the request of EPA and other federal agencies, the NRC published a comprehensive report "*Health Implications of Perchlorate Ingestion*" (NRC, 2005). The NRC concluded that perchlorate can affect thyroid function because it is an ion that competitively inhibits the transport of iodide into the thyroid by a protein known as the sodium (Na)/iodide (I) symporter (NIS). Significant inhibition of iodide uptake results in intra-thyroid iodine deficiency, decreased synthesis of key thyroid hormones (Triiodothyronine, T3 and Thyroxine, T4), and increased thyroid stimulating hormone or thyrotropin (TSH). The NRC also concluded that a prolonged decrease of thyroid hormone is potentially more likely to have adverse effects in sensitive populations (people with thyroid disorders, pregnant women, fetuses, and infants).

The NRC recommended the use of a precursor, non-adverse effect (i.e., inhibition of iodide uptake) to derive a reference dose (RfD) for perchlorate. An RfD is defined by EPA as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." The NRC identified a clinical study involving 37 healthy men and women by Greer *et al.* (2002) as the critical study and determined an RfD of 0.7 μg/kg/day for perchlorate. The RfD was based on the No Observed Effect Level (NOEL) of 7 μg/kg/day corresponding to a radioactive iodide uptake (RAIU) inhibition of 1.8 percent and application of an intraspecies uncertainty factor (UF) of 10 to account for differences in sensitivity between the healthy adults in the Greer *et al.,* (2002) study and the most sensitive population, fetuses of pregnant women who might have hypothyroidism or iodide deficiency. The NRC also acknowledged that the RfD may need to be adjusted upward or downward on the basis of future research. The RfD of 0.7 μg/kg/day was adopted by EPA in 2005 (U.S. EPA, 2005a). EPA believes that this RfD is the most scientifically defensible endpoint available at this time for assessing risk from perchlorate exposure.

In October 2008, EPA published a preliminary determination not to regulate perchlorate in drinking water using a health reference level (HRL) of 15 μg/L, which was derived from the RfD of 0.7 μg/kg/day, using a default body weight (70 kg), a default drinking water consumption rate (2 L/day), and a perchlorate-specific relative source contribution (RSC) of 62% for a pregnant woman (U.S. EPA, 2008). The RSC is the percentage of the RfD remaining for drinking water after the other sources of exposure to perchlorate (e.g., food) have been considered. In January 2009, EPA issued an interim health advisory (15 μg/L perchlorate in drinking water) to provide guidance to state and local officials in their efforts to address perchlorate contamination while EPA was continuing to review scientific issues (U.S. EPA, 2009a).

In August 2009, EPA published a supplemental request for comment with a new analysis that derived potential alternative HRLs for 14 life stages, including infants and children. The analysis used the RfD of 0.7 μg/kg/day and life stage-specific body weight and exposure information (i.e., drinking water intake, RSC) (U.S. EPA, 2009b). The HRLs ranged from 1 μg/L to 47 μg/L. In February 2011, EPA published the Final Regulatory Determination to regulate perchlorate under SDWA. The Final Regulatory Determination stated that EPA was evaluating the potential alternative HRLs and considered them to be levels of public health concern for the purposes of final determination (U.S. EPA, 2011a).

Charge to the SAB

The purpose of this white paper is to seek guidance from the SAB on how best to consider and interpret the life stage information, the epidemiologic and biomonitoring data since the NRC report, physiologically-based pharmacokinetic (PBPK) analyses, and the totality of perchlorate health information to derive an MCLG for perchlorate.

Specific Charge Questions

Issue I - Sensitive Life Stages

While studies directly demonstrating the adverse effects of perchlorate in humans are not available, potential effects can be inferred from the mode of action for perchlorate and the literature on thyroid hormone decrements and neurological deficits in various life stages. Perchlorate blocks the transport of iodide into the thyroid gland leading to iodide deficiency and decreased synthesis of thyroid hormones, T3 and T4. Transfer of iodide from blood into the thyroid gland is essential for the synthesis of the thyroid hormones. In its deliberations on the health effects of perchlorate in drinking water, the NRC committee considered pregnant women who might have hypothyroidism or iodide deficiency and their fetuses to be particularly sensitive populations to perchlorate mediated health effects (NRC, 2005).

Based on the discussion in Section IV of the white paper, pregnant women and their fetuses, neonates, infants (breast-fed and bottle-fed) and young children have been identified as life stages of concern for adverse effects due to perchlorate. Significant thyroid perturbations *in utero* are well known to cause neurological deficits in infants and children (NRC, 2005). High turnover rate of thyroid hormones, and low storage capacity in the fetus and neonate make these in particular, sensitive life stages for thyroid hormone perturbations. Furthermore, infants and children, in general, are more susceptible to xenobiotics effects because of low urinary clearance of contaminants, and higher food consumption and drinking water intake per body weight relative to adults (USEPA, 2011b). As in the thyroid gland, perchlorate is actively taken up into mammary tissue via NIS. Perchlorate also competitively inhibits the uptake of iodide into the mammary gland, reducing the amount of available iodide in breast milk. Therefore, breast-fed infants also represent a population of particular concern as they experience a double hit – exposure to perchlorate accumulated in breast milk in addition to a deficiency of iodine in the breast milk. (Kirk *et al.*, 2005; Dasgupta *et al.*, 2008; Valentin-Blasini *et al.*, 2011).

There are currently no data available to directly link perchlorate to neurobehavioral effects in infants and children. How should EPA consider the following life stage factors in deriving an MCLG?

- **Life stage specific differences in body weight and food and drinking water intake;**
- **Differences in greater severity and permanence of potential adverse effects in neonates, infants and young children compared to adults;**
- **Shorter half-life and lower reserves for thyroid hormone in infants compared to adults; and**
- **Intrauterine exposure to perchlorate and impact on thyroid status in fetuses.**

Issue II - Physiologically-Based Pharmacokinetic Evidence

The NRC relied on information on inhibition of RAIU in a small group of healthy, iodine sufficient, adults, similar data are not available for other life stages. With the development of the PBPK model (U.S. EPA, 2009b), it is now possible to provide estimates of the effect of perchlorate on RAIU in different life stages as outlined in white paper Section VI.

The PBPK model predictions can be evaluated in two different ways. The first application is based on a comparison of the relative RAIU inhibition sensitivity at a fixed dose (point of departure, POD of 7 μg/kg/day identified by NRC) for different life stages. One exception in the first application scenario with regard to dosing is that the breast-fed infants received a dose higher than the POD, but lactating mothers received a dose equivalent to the POD. The second application involves comparing RAIU inhibition at a fixed drinking water exposure level (15, 20 and 24.5 ppb) with and without perchlorate contribution via food for various life stages. Thus, the doses for different life stages varied in the second application scenario.

The findings from the first application indicate a greater sensitivity for RAIU inhibition for fetuses and breast-fed infants compared to other life stages/sub populations (Table A-3 of the White Paper). The findings from the second application indicate a RAIU inhibition of 2.2% or less for all life stages when they are exposed to drinking water containing 15 μg/L perchlorate in addition to perchlorate in food (Table A-4 of the White Paper). In the context of significance of RAIU inhibition, NRC determined 1.8% RAIU inhibition was not significant at the POD/NOEL of 7 μg/kg/day for healthy adults, but recommended that a 10-fold uncertainty factor be applied to the POD to protect the fetus of the pregnant woman who might have hypothyroidism or iodine deficiency. However, the doses infants receive when exposed to 15 μg/L perchlorate in water and perchlorate in food are up to 5 times higher than the RfD.

- **How should EPA consider PBPK modeling to derive an MCLG for perchlorate?**

- **What are the strengths and limitations of the two PBPK model results described in this effort?**

Issue III – Epidemiological Evidence

Since the NRC report (2005), a number of epidemiological studies have investigated the association between perchlorate exposure and thyroid hormone perturbations. None evaluated the neurodevelopmental outcomes. The studies reported findings for sensitive life stages of concern: pregnant women, neonates and infants. Several of these studies investigated the association between perchlorate exposure in drinking water and thyroid hormone levels in the US, Israel and Chile (Tellez *et al.*, 2005, Amitai *et al.*, 2007, Steinmaus *et al.*, 2010). The study in Chile (Tellez *et al.*, 2005) reported urinary and serum perchlorate levels in women during pregnancy and post partum (a longitudinal cohort study). However, perchlorate assignment to subjects was based solely on geographical location. Other studies that examined the association between perchlorate and thyroid hormone levels included urinary perchlorate concentrations as biomarkers of exposure (Blount *et al.*, 2006; Pearce *et al.*, 2010, 2011). Using NHANES 2001-2002 data, Blount *et al.* (2006) demonstrated a perchlorate-related increase in TSH and decrease in T4 in women >12 years of age with urinary iodide <100 μg/L. Pearce *et al.* (2010, 2011) did not find an association between urinary perchlorate and thyroid hormone perturbations in first trimester pregnant women. Differences in study designs, numbers and age of subjects, exposure assessment approaches, and statistical methods may explain the mixed findings among these studies. The studies published in the literature since the NRC (2005) review are described in Section VII and

Table A-5 of the white paper. The new epidemiological evidence may inform bounding of the possible life stage-specific MCLG estimates derived in the White Paper (Table-1).

- **How should EPA consider the post-NRC epidemiology data in deriving an MCLG?**

Issue IV – Integration of Information

The primary action of perchlorate exposure is on the thyroid gland, where perchlorate inhibits the transport of iodide from the blood into the thyroid gland which in turn can lead to perturbations in the synthesis of thyroid hormones. Perturbations in thyroid hormones during critical stages of development lead to permanent neurological deficits in children (NRC, 2005). EPA generally derives an MCLG on the basis of the RfD. EPA believes that the NRC derived RfD of 0.0007 mg/kg/day (0.7 µg/kg/day) for perchlorate is the most scientifically defensible endpoint available at this time for deriving an MCLG. In deriving the RfD, the NRC applied an intraspecies factor of 10x to protect the fetuses of pregnant women who might have hypothyroidism or iodide deficiency. The UF 10 can be further subdivided into a $UF_{TK} = 10^{1/2} = 3.16$ (generally rounded to 3) to account for differences in internal dosimetry due to toxicokinetic differences, and a $UF_{TD} = 10^{1/2} = 3.16$ (generally rounded to 3) to account for differences in toxicodynamics. This convention is used by EPA in the absence of compound-specific data as is the case with perchlorate.

At a fixed dose of 7 µg/kg/day, the first application of PBPK model findings indicate 6.7x, 2.6x, 7.8x, and 1.1x greater sensitivity for RAIU inhibition for GW 40 fetuses,7 day breast-fed infants, 7-day bottle-fed infants and children from 6 months to 2-years, respectively, as compared to adults (Table A-3 of the White Paper). It was not possible to estimate sensitivity in younger than term fetus. The second use of PBPK modeling indicates a RAIU inhibition of 2.2% or less for all life stages when they are exposed to drinking water containing 15 µg/L perchlorate in addition to perchlorate in food (Table A-4 of the White Paper). In the context of significance of RAIU inhibition, NRC determined 1.8% RAIU inhibition not significant for healthy adults. However, the doses infants receive when exposed to 15 µg/L perchlorate in water and perchlorate in food are up to about 5 times higher than the RfD.

As discussed previously the mixed pattern of observations in the epidemiologic studies which investigated the association between perchlorate exposure and thyroid perturbations since the 2005 NRC review is not surprising in light of their different study designs, numbers and age of subjects, exposure assessment approaches, and statistical methods. In an ecological study, Steinmaus *et al.* (2010) found increased TSH levels in neonates when the mothers were exposed to perchlorate concentrations above 5 µg/L in drinking water. Using 2001-2002 NHANES data, perchlorate-related increases in TSH and decreases in T4 were demonstrated in women >12 years of age with urinary iodide <100 µg/L (Blount *et al.*, 2006). The changes in thyroid hormone levels in the NHANES analyses were observed at a mean perchlorate intake level of approximately 0.1 µg/kg/day (including food and drinking water) reported by Huber *et al.* (2011) for the NHANES populations, suggesting thyroid hormone perturbations at a perchlorate intake level less than the RfD determined by NRC (2005). The perchlorate dose estimated from Huber *et al.* (2011) is consistent with that reported from other biomonitoring studies and analyses reported in Section VIII and Table A-6 of the White Paper. Other studies of pregnant women or neonates did not report associations between residence in a city with perchlorate in drinking water supplies or between urinary perchlorate at similar or higher exposure levels than those estimated for Blount *et al.* (2006) (Tellez *et al.*, 2005; Amitai *et al.*, 2007; Pearce *et al.*, 2010, 2011). Together the results of these studies may serve as a means to bound the drinking water exposure range of concern, and assist in determining where within the range of potential MCLGs an appropriate regulatory value can be set.

- **How can EPA best use the total body of information to derive a health protective MCLG, while considering the results of epidemiology and biomonitoring data in establishing bounds on potential values?**

- **How can EPA use the available data to estimate reductions in adverse health effects (i.e., dose response) that are likely to result from reducing perchlorate levels in drinking water?**

APPENDIX B: Critique of Recent Epidemiological Data for Deriving a Perchlorate MCLG

Epidemiologic studies published since the 2005 NRC report, *Health Implication of Perchlorate Ingestion,* are insufficient to guide causal inference with regard to the association between perchlorate exposure and thyroid dysfunction. This conclusion is based on methodological inconsistencies and limitations pertaining to study design, exposure assessment, samples size, and statistical modeling. Each of these issues is discussed in detail in this Appendix.

Study design

The prototypical epidemiologic study is a randomized controlled trial. When the primary study question is whether perinatal exposure to an environmental chemical adversely affects child cognitive and behavioral development, observational studies must suffice. The ideal observational study to identify potential effects of perinatal perchlorate exposure on child health is not difficult to conceive, although it would be large, expensive, logistically challenging, and take at least 10 years to complete. Ideally, the study would, from the first trimester of pregnancy, prospectively collect serial urinary biomarkers of maternal prenatal perchlorate exposure, serial serum biomarkers of maternal prenatal thyroid function (including TSH, fT4, and thyroid antibodies), and serial urinary maternal prenatal biomarkers of the related compounds iodide, nitrate, and thiocyanate. To determine the relative source contributions of perchlorate in drinking water and perchlorate from other sources, such as food or prenatal vitamins, serial drinking water and dietary measures like a food frequency questionnaire, 24-hour dietary recall, or duplicate plate, must be included and coincide with the collection of exposure biomarkers. Once the child is born, perchlorate, iodide, nitrate, thiocyanate, and thyroid function must be serially monitored in the child. Breast milk, formula, and eventually early solid foods should be assayed for goitrogens. Beginning at birth the child's development must be assessed and then monitored every 2 to 3 years by performance on standardized neurobehavioral assessments. The home environment should be evaluated by trained research personnel, the mother's IQ should be measured, and other known predictors of child IQ and behavior, for instance lead exposure, should be obtained. The study can conclude with a final round of cognitive and behavioral testing when the child reaches 7 – 9 years of age.

When even an observational study of perinatal perchlorate exposure and child development is such a massive undertaking, researchers look to other study designs, data collected for other purposes, and interim outcomes (e.g., maternal prenatal thyroid dysfunction rather than impaired child cognitive skills) to address the study question. Unfortunately, the epidemiologic studies of health effects of environmental perchlorate exposure are insufficient to guide causal inference even for the interim question of whether exposure to perchlorate results in thyroid dysfunction.

Thirteen epidemiological studies published since the monograph *Health Implications of Perchlorate Ingestion* (NRC 2005) and assessing thyroid function can be divided into 2 groups based on the level of measurement of the exposure. Four ecological studies present environmental measures of perchlorate in drinking water based on residential location (Tellez 2005: Buffler 2006; Amitai 2007; and Steinmaus 2010). Nine studies present individual measures of urinary perchlorate exposure (Cao 2010; Pearce et al. 2010, 2011, 2012; Leung 2012; Blount 2006; Steinmaus 2007; Schreinemachers 2011; Mendez 2012). Ecological studies compare groups, not individuals. Defining exposure based on group level characteristics, such as water district, is a variation on the ecological study design. These types of studies are often the first investigative hypothesis-testing tool. They can lend credence to a new hypothesis and provide important preliminary data for planning future studies, but the ecological fallacy precludes any causal interpretation. The ecological fallacy occurs when population level associations are also assumed to occur at the individual level. For these studies, specifically, the fallacy occurs with the assignment of exposure: someone with a residence in a city with high levels of perchlorate in drinking water (person A) is assumed to be exposed to more perchlorate than someone with a residence in a city with low levels of perchlorate in drinking water (person B). There are several reasons why this scenario may be untrue. While ones' official residence at the time of exposure is defined for the study is located in the high-exposure city, this may be a new residence (i.e., the subject may have moved during pregnancy so the address listed on a birth certificate is not the address where the majority of the pregnancy occurred). The subject may have an official residence, but actually spend the majority of time at a different location. The subject may not drink tap water or may use filtered tap water (i.e., under the counter reverse osmosis filters remove perchlorate) or use a private well. Conversely, for the same reasons why person A may not actually be exposed to high levels of perchlorate through drinking water, person B may be exposed to higher than expected levels for someone with a residence in a city with low levels of perchlorate in drinking water.

For perchlorate studies where exposure is an ecological measure based on drinking water source, there are additional concerns that may lead to further exposure misclassification. First, drinking water typically accounts for an estimated 20% of total perchlorate dose (Huber 2010). Consequently, estimating total perchlorate exposure solely by drinking water source may be inaccurate. Second, perchlorate levels in drinking water may not be constant even though studies using ecological exposure measures define them as such (e.g., person A either does or does not reside in a high exposure location). Buffler et al. notes that in southern California, the proportion of Colorado River water used for drinking water varies seasonally (2006). In water supply systems reliant on Colorado River water, the level of perchlorate in the drinking water may change as more or less river water is diverted into the drinking water system. Categorical assignment of high/medium/low exposure water districts may not be true over time and season.

Overall, the four studies examining ecological measures of perchlorate exposure in drinking water in relation to thyroid function, regardless of whether or not they show an association, are insufficient to determine a causal association between perchlorate in drinking water and thyroid function nor are they useful for determining direct inputs for deriving an MCLG for perchlorate in drinking water. Two of these studies, however, may provide complementary evidence to assess the broad-based public health impact of regulating perchlorate in municipal water supplies. These two studies (Buffler 2006; Steinmaus 2010) linked data on perchlorate in municipal drinking water measured by the California Drinking Water Program to thyroid hormone levels and primary congenital hypothyroidism, as assessed through the California Newborn Screening Program. Studies using a similar design can provide population-level disease (primary congenital hypothyroidism) prevalence in relation to the concentration of perchlorate in municipal water. Using Buffler 2006 and/or Steinmaus 2010 to describe the "pre-regulation" rates of disease in exposed and unexposed communities, future studies using a similar design may broadly inform the public health implications of regulating perchlorate in drinking water. These two studies have been noted because of the broad geographic area represented (California) and the large sample size (>300,000 newborns).

Cross-sectional studies using individual level measures of both exposure and outcome are often the next investigative tool for examining an association. With cross-sectional studies, there is an individual measure of exposure and an individual measure of the outcome, but the exposure and outcome are assessed at the same point in time so causality cannot be inferred. With a cross-sectional study, there is no way to know whether the exposure preceded the outcome and consequently no way to determine whether the exposure is a causal factor in development of the outcome. Nonetheless, cross-sectional studies may be useful for elucidating relationships.

Of the nine cross-sectional studies, three use NHANES data from 2001-2002 (Blount et al. 2006; Steinmaus 2010; Schreinemachers 2011). Mendez and Eftim used NHANES 2007 – 2008 (2012). Blount observed biologically plausible and consistent associations between increased urinary perchlorate concentration and increased TSH and decreased T4 among women with low urinary iodide concentration. Steinmaus carried these analyses forward and observed that this relationship appeared to be strengthened as urinary thiocyanate concentration increased. Mendez also showed inverse associations between levels of perchlorate and T3 and T4. In these analyses, however, TSH, thyroid antibodies, and iodine were adjusted for in the model although their role may be better treated as stratification variables (see Statistical Model Misspecifications below). Schreinemachers used indirect measures of thyroid function (HDL cholesterol, hemoglobin, hematocrit), which may be more relevant to the thyroid's role in metabolic pathways rather than neurobehavioral development.

Only one of the five non-NHANES cross-sectional studies replicated the association between higher urinary perchlorate concentration and higher TSH among infants with lower urinary iodide levels (Cao 2010) .This study, however, measured thyroid hormones in urine, not serum and the correlation between thyroid hormones in urine and serum is low (Cao 2010). Unexpectedly, higher urinary perchlorate was also associated with higher T4. None of the remaining four cross-sectional studies observed associations between urinary perchlorate levels and thyroid function in pregnant women (Pearce et al. 2010, 2011, 2012) or in infants (Leung 2012).

Overall, there is little consistency in the study design, methods, or conclusions of the 9 cross-sectional studies. Many of the studies suffer from a small sample size, several have poorly specified statistical models (see discussion below), and there is inconsistent treatment of urinary creatinine, iodide status, and presence of thyroid antibodies. Given these methodological concerns, the lack of concordance in results is not surprising. A prospective study using individual level measures of both exposure and outcome is needed to truly determine a causal link between perchlorate exposure and either thyroid function or child neurobehavioral development. There are no prospective studies examining the association between individual urinary biomarkers of perchlorate exposure and individual serum biomarkers of thyroid function.

One final piece needed to fully interpret studies using spot urine specimens for determination of perchlorate and iodide is an improved understanding of the temporal variability of urinary measures of perchlorate, iodide, nitrate, and thiocyanate. Variability incorporates both daily variation in urine excretion and variation in exposure due to a variable diet. A thorough review and synthesis of the literature examining how well a single spot urinary measure of these compounds reflects long term exposure patterns is advised.

Misspecification of Statistical Models in Epidemiologic Studies

Potential statistical model misspecification is an important consideration when interpreting the results of seven studies published since the 2005 NRC report that have incorporated individual-level measures of perchlorate exposure and serum thyroid hormone concentrations (Blount et al. 2006; Steinmaus et al. 2007; Mendez and Eftim 2012; Pearce et al. 2010, 2011, 2012; Leung 2012). Concerns relate to: (1) modeling perchlorate exposure as a linear term when the relationship with health outcomes may not be linear, (2) proper assessment of suspected effect measure modifiers, (3) inappropriately controlling for causal intermediates, (4) inadequate assessment of confounders leading to over-adjustment for factors suspected to be associated with the thyroid hormone outcomes but not with perchlorate exposure, and (5) suitable methods for modeling co-exposures to other goitrogens or thyroid hormone disrupters like thyroid antibodies. These elements are addressed in more detail as they relate to specific studies.

All epidemiologic studies of urinary perchlorate concentrations and thyroid function published after the 2005 NRC report have reported results of linear regression models or generalized additive mixed models (GAMM) specifying perchlorate exposure as a linear term predicting continuous measures of thyroid function (Mendez 2012). Approaches that assume a monotonic linear relationship between perchlorate and thyroid hormone concentrations may fail to reveal other plausible patterns of association such as effects that occur only after some exposure threshold is reached, low dose effects that plateau at some point along the exposure continuum, or other possible U-shaped or inverted U-shaped patterns. Evidence for non-linear associations with perchlorate was examined by adding a square of the log of perchlorate to the linear regression models (Blount et al. 2006) and by using GAMM to determine whether smoothing of the perchlorate term provided a better model fit (Mendez 2012). However, the extent to which other patterns of association were explored in these and other studies is not evident. Furthermore, hypothyroxinemia during the first trimester of pregnancy rather than overt thyroid disease is increasingly of interest because even hypothyroxinemia may result in irreversible neurodevelopmental deficits in the offspring (Delahunty 2010). However, existing studies have not incorporated this endpoint.

Some studies have considered thyroid antibodies in their analyses. The thyroid antibodies thyroglobulin antibody (TgAb), thyroid stimulating hormone receptor antibody (TSH-RAb), and thyroid peroxidase antibody (TPOAb) can interfere with thyroid hormone synthesis via humoral and cell-mediated mechanisms leading to clinical or subclinical hypothyroidism (Sinclair 2006). Individuals with hypothyroidism may be more susceptible to additional thyroid disruption, such as that occurring when exposed to perchlorate. Hollowell et al. (2002) estimated the prevalence of thyroid antibodies in the NHANES 1988-1994 sample. In the overall study population, 13.0% and 11.5% had detectable TPOAb and TgAb, respectively. Among the disease-free population, 11.3% (TPOAb) and 10.4% (TgAB) were antibody-positive. Antibody-positive participants were more likely to be female and among females, antibody prevalence increased significantly with age. If the effect of perchlorate on thyroid function differs among people with thyroid antibodies, antibody status should be measured in studies of perchlorate effects and evaluated as a potential effect modifier in the statistical modeling (see detailed discussion below).

The seven studies that use individual-level biomarkers of exposure can be grouped according to their target populations which include women during the first trimester of pregnancy (Pearce et al. 2010, 2011, 2012), infants at 1-3 months of age (Leung 2012), and the general U.S. population as represented by NHANES (Blount 2006; Steinmaus 2007; Mendez 2012).

The three cross-sectional studies of pregnant women by Pearce and colleagues (2010, 2011, 2012) have reported no observed associations between urinary perchlorate concentrations and first-trimester thyroid hormone levels in populations from California, Argentina, Wales, Italy, and Greece. While the studies were generally similar, the outcome assessment in one of them differed from the others in that fT4 and TSH levels were assessed as multiples of the median (Pearce et al. 2010). All of these studies used linear regression models adjusted for urinary iodine and TPOAb as well as other factors selected for their suspected associations with thyroid hormone status. Adjustment for iodine concentrations, TPOAb status and other indicators of potential susceptibility, however, deserves careful consideration. The rationale provided for controlling for both iodine and TPOAb titers is that women with low iodine or TPOAb may be more susceptible to the effects of perchlorate exposure on thyroid function. If the effect of perchlorate is anticipated to differ across defined subgroups, it is appropriate to examine the factor as a potential effect measure modifier by using stratification or interaction terms rather than adjusting for the factor as a control variable. Otherwise, associations that may be present in defined subgroups could be obscured when these subgroups are combined for analysis. While these studies examined correlations between urinary perchlorate and thyroid hormones among women with urinary iodine concentrations < 100 μg/L, multivariable regression analyses of perchlorate exposure were not examined for interactions with iodine status. This evaluation was presumably limited by small sample sizes in the defined strata. The Pearce et al. study of 134 pregnant women from California and 107 pregnant women from Argentina reported examining a multivariable analysis restricted to TPOAb negative women from the combined study populations (2011). Results were not shown but were reportedly similar to results obtained from the unrestricted analyses of all women combined. Analyses among the potentially susceptible population of TPOAb positive women were likely limited due to small numbers. The study of 134 pregnant women from Greece reported examining and observing no interaction between urinary perchlorate and TPOAb positivity, although the statistical power to detect such interactions was again limited by the small sample size (Pearce et al. 2012).

It is noteworthy that Pearce et al. (2010) also controlled for smoking status defined as cotinine >500 ng/ml or thiocyanate concentrations (in separate models). The selected cotinine cutpoint of >500 ng/ml would represent relatively heavy smoking and would not successfully control for more modest levels of active smoking commonly indicated by urinary cotinine concentration of 15 ng/ml or 50 ng/ml. However, if the effect of perchlorate on thyroid function is suspected to be greater among smokers than non-smokers as reported by Steinmaus et al., then evaluation of potential interactions with smoking would precede assessment of confounding (2007). Other potential confounders such as age, race, body mass index (BMI), or creatinine concentrations were not considered in these models. Of particular note, there was no evaluation of confounding or effect measure modification by gestational age to consider the potential impact of changes in increasing fT4 and decreasing TSH concentrations that occur during the first trimester due to increased circulating concentrations of human chorionic gonadotropin and estrogen (Morreale de Escobar 2008). While the explanation for a potential association between perchlorate and gestational age remains unclear, gestational age was identified as a confounding factor of the perchlorate and thyroid hormone association among pregnant women in Greece (Pearce et al. 2012).

Another consideration is the potential bias that could be introduced by controlling for covariates that lie on the causal pathway between perchlorate exposure and thyroid function. The mechanism by which perchlorate may alter thyroid hormone status is by competitively inhibiting iodide uptake. This leads to the question of whether urinary iodide concentrations would be a proxy for intra-thyroid iodine deficiency, which lies on the causal pathway between perchlorate and thyroid hormone alterations. Inappropriately controlling for a causal intermediate can distort results by underestimating the true exposure effect, a result of partial or complete control of effects that occur through this pathway. Pearce et al. 2010 controlled for urinary iodide concentrations in fT4 models, but reported that urinary iodide concentrations were removed from the TSH models because iodide concentrations were not a significant predictor of TSH and the model was not significant when urinary iodide was included (Pearce et al. 2011). All linear regression models in the remaining two Pearce et al. studies (2011, 2012) controlled for urinary iodide. Results were not available to compare multivariable models with and without control for these factors to determine if adjustment for iodide altered point estimates.

According to power analyses provided in the Pearce et al. publications, the studies of first trimester thyroid function were powered to detect stronger correlations than those observed; thus, the sample sizes were not sufficient to confirm the absence of more modest associations (2010, 2010, 2012).

Three studies have evaluated urinary perchlorate associations with thyroid function in NHANES study populations (Blount et al. 2006; Steinmaus et al. 2007; Mendez 2012) . The analysis by Blount et al. is considered one of the most definitive studies to date, due to the large nationally representative sample size and use of individual measures of urinary perchlorate concentrations. In the analysis of NHANES 2001-2002 data, Blount et al. observed no associations between perchlorate exposure and thyroid function in men. However, in women with urinary iodine <100 μg/L, log-transformed urinary perchlorate concentrations were positively associated with TSH concentrations and negatively associated with T4 concentrations. In women with urinary iodine ≥ 100 μg/L, perchlorate remained positively associated with TSH, but was not statistically associated with T4 concentrations. This was the first study to separately evaluate associations among women with insufficient iodine intake (urinary iodine <100 μg/L). The analysis by Blount et al. evaluated an extensive list of covariates selected based on known or suspected associations with T4 or TSH concentration. These included age, race/ethnicity, BMI, estrogen use, menopausal status, pregnancy status, premenarche status, serum C-reactive protein, serum albumin, serum cotinine, hours of fasting, urinary thiocyanate, urinary nitrate and selected medication groups. Models were also controlled for log creatinine to adjust for variability in urine dilution. The authors aimed to assess effects of perchlorate that were independent of other factors known to alter thyroid function. However, when the aim is to estimate causal associations, the goal is to control for those factors that may distort the true exposure-disease association due to mutual associations with the perchlorate exposure and thyroid hormone function outcome. Unnecessarily adjusting for factors that are associated only with thyroid function (and, therefore are not acting as confounders) can result in loss of precision; however, gains in precision can sometimes occur depending on the type of statistical model and strength of association with the outcome variable (Schisterman et al. 2009).

Steinmaus et al. extended the NHANES 2001-2002 analyses reported by Blount et al. in 2006 to examine interactions between perchlorate and smoking and between perchlorate and thiocyanate on thyroid function (2007). In women with urinary iodine concentrations < 100 μg/L, the negative association between log perchlorate and T4 was stronger in self-reported smokers, those with high serum cotinine concentrations, and those with higher urinary thiocyanate levels than in those without these characteristics. Similar interactions were not observed for log TSH. Although the T4 models were adjusted for fasting time, kilocalories, BMI, c-reactive protein, nitrate, race, estrogen use, pregnancy and menopause status, the authors reported that in most of the regression models only modest differences were observed between the adjusted and unadjusted coefficients. As in the Blount et al. study, it is unclear how some of the covariates may also be related to perchlorate exposure such as c-reactive protein, estrogen use, and menopause status, but controlling for extraneous covariates that are not confounders and not intermediates on the causal pathway would likely impact model precision but not bias results.

While the previous NHANES analyses were limited to assessments of total T4 and TSH, Mendez and Eftim's (2012) analysis of NHANES 2007-2008 data incorporated total and free T4 and T3 concentrations. The results of generalized additive mixed models (GAMM) indicated log-transformed perchlorate concentrations were negatively associated with total T4 and free T3 in both males and females. In acknowledgment of the mutual effects of TSH, T3 and T4 levels on one another due to the negative feedback loop in the hypothalamic-pituitary-thyroid axis, the regression models in this study were controlled for TSH concentrations. However, TSH alterations may be a common effect of both the exposure (perchlorate) as well as the outcome (T4 concentrations); thus, the observed associations adjusted for TSH concentrations could be the result of collider-stratification bias, which is a form of selection bias that can produce spurious associations when controlling for a shared effects (Schisterman et al. 2009). Other covariates controlled in the analysis included thyroid antibodies and creatinine-adjusted urinary iodine, thiocyanate and nitrate and other environmental contaminants such as phthalate metabolites and bisphenol A. The covariates retained in final models were selected on the basis of statistical significance of associations with thyroid hormone levels; thus, confounding of the perchlorate-thyroid hormone association was not assessed directly, as in other studies, and unnecessary adjusting for non-confounders could reduce the precision of the point estimates (Schisterman et al. 2009). Of note, urinary iodine and thyroid antibodies were controlled in the analyses and were not assessed for potential effect measure modification.

Uncertainties exist regarding the optimal method for considering co-exposures to other goitrogens such as thiocyanate (including exposure occurring through tobacco exposure) and nitrate, which share the same mode of action as perchlorate. Studies have predominantly addressed this concern by controlling for urinary concentrations of other contaminants in multivariable models when the data are available for thiocyanate (Blount 2006; Mendez 2012; Pearce et al. 2010, 2012; Leung et al. 2012), nitrate (Blount 2006; Steinmaus 2007), cotinine (Pearce et al. 2010) or self-reported smoking (Leung 2012). Some studies, however, addressed the question by evaluating interactions between perchlorate and thiocyanate (Steinmaus 2007; Pearce et al. 2012) and between perchlorate and smoking (Steinmaus 2007). These inconsistencies emphasize the need for more in-depth evaluation of co-exposures, including consideration of assessment of cumulative exposure.

The only study of infant thyroid function to incorporate individual measures of perchlorate exposure was conducted by Leung et al. (2012). This cross-sectional study of 64 (partially or exclusively breast-fed) infants ages 1-3 months reported no association between serum TSH or fT4 in infants and perchlorate concentrations in breast milk, maternal urine, and infant urine. The multivariable linear regression models controlled for thiocyanate (presumably measured in the same medium), maternal age, ethnicity, smoking status, iodine-containing prenatal multivitamin use and supplemental infant formula use. The effects of infant urinary perchlorate on infant serum fT4 and TSH were not statistically significant and the small effect sizes were interpreted by the authors as clinically insignificant changes. The small sample size, however, limits statistical power as well as precision of the point estimates.

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APPENDIX C: General Comments on Integration of Information

Risk-based regulation that rests on quantitative analyses is designed to integrate disparate types of data and information for hazard, exposure and risk. For any given assessment, some of the available data will be of poor or lesser quality or of limited relevance, precluding their use for quantitative analyses. Therefore the agency must employ transparent, rigorous review criteria and clear presentation of information to justify the data and methods selected for use in developing risk-based values such as MCLGs (NRC, 2011). The SAB considered the topic of 'integration of information' in this more general sense and offers the following recommendations for integration of the available data and information to guide its development of the perchlorate MCLG.

> Framework to Summarize Data Evaluation and Application
>
> 1) Critically evaluate the quality and content of each type of information in a transparent manner (may need to address each study or component of the larger 'dataset', e.g., life-stage specific intake estimates). Document:
>   a. Strengths
>   b. Limitations
>   c. Information on variability
>   d. Key uncertainties of the information
> 2) Define or describe the contribution of the information towards qualitative or quantitative understanding of perchlorate exposure, biological sensitivity, variability, toxicity and ultimately risk. Include discussion of how specific characteristics limit or support the contribution.

As EPA builds on the analyses presented in the White Paper and incorporates the panel's recommendations, the agency should consider the advice of the NRC Committee in its Review of the Draft IRIS Assessment on Formaldehyde (NRC 2011) to improve the clarity of assessment documents. The agency needs an a priori approach for inclusion or exclusion and weighting of studies. Specifically the panel recommends that EPA develop a structured framework to capture the key points of the evaluation and application of each type of data or model used in the development of the perchlorate MCLG, as well as the strengths, limitations and uncertainties associated with each. This framework should be incorporated into the text, at the end of each relevant section. The text box below describes the elements of such a framework discussed by the panel. These elements can be supplemented with additional elements from the agency's guidance documents and current practices of data and weight of evidence evaluation. In applying the framework to the epidemiological data, the panel recommends that EPA take advantage of available evaluation tools such as Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)[7] or Grading of Recommendations Assessment, Development and Evaluation (GRADE)[8], as appropriate.

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[7] Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) http://www.strobe-statement.org/index.php?id=available-checklists [accessed July 30, 2012].

[8] Grading of Recommendations Assessment, Development and Evaluation (GRADE) http://www.gradeworkinggroup.org/index.htm [accessed July 30, 2012].

The draft framework also reflects the recommendations of the NRC as presented in Science and Decisions: Advancing Risk Assessment (NRC 2009), specifically the necessity to estimate and document the uncertainties in all aspects of an assessment including doses, exposures and outcomes.

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Message

From: Kirby, Kevin [KIRBY.KEVIN@EPA.GOV]
Sent: 5/29/2013 9:05:08 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: FW: U.S. Chamber Request for Reconsideration of IQA Request for Correction Regarding "Drinking Water: Regulatory Determination on Perchlorate" (RFC 12004)
Attachments: 130528_Comments_RFR-RegulatoryDeterminationOnPerchlorate_EPA_w_original_and_appeal.pdf

Hi Eric,

Just wanted to let you know that the US Chamber has resubmitted this petition for reconsideration on the Regulatory Determination on Perchlorate. This time, the process it tips off resides at the AA level, chaired by the CIO.

More to come, so stay tuned,
Kevin

Kevin J. Kirby, Enterprise Data Architect
EPA Quality Staff, OEI, US EPA
(202) 566-1656 desk
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From: Kimberlie Orr [mailto:Orr.Kimberlie@epamail.epa.gov]
Sent: Wednesday, May 29, 2013 4:36 PM
To: Kirby, Kevin
Subject: Fw: U.S. Chamber Request for Reconsideration of IQA Request for Correction Regarding "Drinking Water: Regulatory Determination on Perchlorate" (RFC 12004)

Hi, KK. You may want to let the information owners you worked with and OGC know that this has shown up. I will get it prepared for posting and weekly reporting next week. I can also let OMB know that it has come in (once I post it). KO

This one will require another PowerPoint. I will get the template for that ready.

Kimberlie R. Orr
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Quality Staff (2811T)
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----- Forwarded by Kimberlie Orr/DC/USEPA/US on 05/29/2013 04:33 PM -----

To: Group Quality@EPA
cc: "Holman, Keith" <KHolman@USChamber.com>

Subject: RE: U.S. Chamber Request for Reconsideration of IQA Request for Correction Regarding "Drinking Water: Regulatory Determination on Perchlorate" (RFC 12004)

Please use this attachment instead -- it combines the initial Request for Correction, EPA's response, and the Request for Reconsideration. Thank you.

Shea

--
Shea Bettwy
U.S. Chamber of Commerce
T: (202) 463-5392

From: Bettwy, Shea
Sent: Tuesday, May 28, 2013 3:56 PM
To: 'quality@epa.gov'
Cc: Holman, Keith
Subject: U.S. Chamber Request for Reconsideration of IQA Request for Correction Regarding "Drinking Water: Regulatory Determination on Perchlorate" (RFC 12004)
Importance: High

Dear Madam or Sir:

Please find the attached Request for Reconsideration from the U.S. Chamber of Commerce. Thank you.

Shea

--
Shea Bettwy | Committee Coordinator
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(See attached file: 130528_Comments_RFR-RegulatoryDeterminationOnPerchlorate_EPA_w_original_and_appeal.pdf)

CHAMBER OF COMMERCE
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September 18, 2012

Information Quality Guidelines Staff (Mail Code 2811R)
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quality@epa.gov

Re: Request for Correction: "Drinking Water: Regulatory Determination on Perchlorate"

The U.S. Chamber of Commerce (Chamber) submits this request for correction (RFC) of information developed and relied upon by the Environmental Protection Agency (EPA or Agency) to support its determination to regulate perchlorate under the Safe Drinking Water Act (SDWA). 76 Fed. Reg. 7762. As described by this RFC, EPA's determination to regulate perchlorate improperly relied upon data that is not objective. The Chamber seeks correction of this information, as it complies with neither the Information Quality Act (IQA) as implemented under Office of Management and Budget (OMB) guidelines nor EPA guidelines. Treasury & General Governmental Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554 § 515(a); 44 U.S.C. § 3516 (notes).

EPA's reliance on flawed, non-objective data sunders the factual foundation of its determination to regulate perchlorate.

To regulate a drinking water contaminant under the SDWA, EPA must find that the contaminant occurs with a frequency and at levels of public health concern in public water systems. 42 U.S.C. §. 300g-1(b)(1)(A)(ii). Had EPA relied upon objective occurrence data available at the time of the regulatory determination, it is likely that EPA would not have been able to make the required finding, and thus would not have made a corresponding decision to regulate perchlorate.

1. Requester Identity and Information

The Chamber is the world's largest business federation, representing the interests of more than three million businesses and organizations of every size, sector, and region. The Chamber's broad membership base includes large and small companies—more than 96 percent of Chamber members are small businesses with 100 employees or fewer—trade associations, and chambers of commerce.

The Chamber includes member companies engaged in the use, manufacture and sale of products containing perchlorate. Other Chamber members rely on water supplies delivered by public water systems of all sizes. A number of these companies will be directly affected by EPA's regulatory determination, guidance and other actions that utilize the erroneous information this RFC seeks to correct. And nearly every Chamber member would be subject to higher costs for core business activities, necessitated by the imposition of costs resulting from unnecessarily expensive perchlorate regulations.

Pursuant to the IQA, the Chamber is an affected person that seeks to obtain correction of information maintained and disseminated by EPA that does not comply with OMB and EPA Guidelines. The Chamber's main point of contact for this RFC is:

William L. Kovacs
Senior Vice President, Environment, Technology & Regulatory Affairs
U.S. Chamber of Commerce
1615 H Street, NW
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2. Description of the Information

EPA published its regulatory determination for perchlorate on February 11, 2011. 76 Fed. Reg. 7762. EPA relied on data collected during the first Unregulated Contaminant Monitoring Rule (UCMR 1) in making its regulatory determination. EPA stated that it "collected and analyzed drinking water occurrence data for perchlorate from 3,865 PWSs [public water systems] between 2001 and 2005 under UCMR 1." 76 Fed. Reg. 7764.

EPA made the following findings based on the UCMR 1 data:

- "EPA found that 160 (approximately 4.1 percent) of the 3,865 PWSs that sampled and reported had at least 1 analytical detection of perchlorate (in at least 1 sampling point) at levels greater than or equal to the MRL [method reporting level] of 4 ug/L." 76 Fed. Reg 7764-65 & Table 1.

- EPA estimated the number of people exposed to perchlorate above various concentrations levels. For example, EPA estimated that 5.1 million people (central value estimate) were served by a public water system that had a least one detection of perchlorate above 4 ug/L, and that 3.0 million people (central value estimate) were served by a public water system that had at least one detection above 6 ug/L. 76 Fed. Reg. 7765 & Table 2. EPA provided similar estimates at concentration levels of 9, 14, 19 and 23 ug/L.

- "Based on the data in Table 1 and the range of HRLs [health risk levels], EPA has determined that perchlorate is known to occur or there is a substantial likelihood that it will occur with a frequency and at levels of public health concern." 76 Fed. Reg. 7765.

The information contained in the regulatory determination for perchlorate, described above, meets the OMB definition of "information." "'Information' means any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic . . . ." OMB Guidelines § V.5; 67 Fed. Reg. 8460. The UCMR 1 data contained in the regulatory determination was presented in textual, tabular and numerical form.

The information at issue also meets the OMB definition of "influential" information. "Influential" means: "that the agency can reasonably determine that the dissemination of the information will have or does have a clear and substantial impact on important public policies . . . ." OMB Guidelines § V.9; 67 Fed. Reg. 8460. EPA directly relied upon the UCMR 1 data in making findings regarding the occurrence of perchlorate in public water systems and in determining to regulate perchlorate under the SDWA. OMB has stated that "influential information" should be held to a heightened standard of quality. 67 Fed. Reg. 8452.

3. How the Information Does Not Comply

In order for data to have the requisite quality, it must be accurate, reliable and unbiased. According to the OMB Guidelines: "'Quality' is an encompassing term comprising utility, objectivity, and integrity." OMB Guidelines § V.1; 67 Fed. Reg. 8459. Further: "'Objectivity' involves two distinct elements, presentation and substance." OMB Guidelines § V.3; 67 Fed. Reg. 8459. With regard to substantive objectivity: "'objectivity' involves a focus on ensuring accurate, reliable, and unbiased information." OMB Guidelines § V.3.b; 67 Fed. Reg. 8459.

The OMB Guidelines also state that in "a scientific, financial or statistical context, the original and supporting data shall be developed using sound statistical and research methods." *Id.* With respect to the use of data, the preamble to the final OMB Guidelines states that:

> We note, in the scientific context, that in 1996 the Congress, for health decisions under the Safe Drinking Water Act, adopted a basic standard of quality for the use of science in agency decision making. Under 42 U.S.C. 300g-1(b)(3)(A), an agency is directed, "to the degree that an Agency action is based on science," to use "(i) the best available peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) ***data collected by accepted methods*** or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)."

67 Fed. Reg. 8457 (emphasis added). OMB included these congressional standards in its Guidance by reference and made them applicable to all agencies subject to the OMB Guidelines. 67 Fed. Reg. 8557. *See also,* OMB Guidelines § V.3.b.ii.C; 67 Fed. Reg. 8560. As a result, the data used in making the regulatory determination for perchlorate was required to be collected by accepted methods or, in certain circumstances, by best available methods.

As discussed in more detail below, a substantial portion (31 percent) of the UCMR 1 data, which EPA relied upon in deciding to regulate perchlorate, was not collected by the accepted method, as described in the UCMR regulations. Data that is not collected in conformance with accepted methods is not reliable. In addition, recent, comprehensive data collected from public water systems in California (which was available at the time the regulatory

determination was made) demonstrates that the occurrence of perchlorate in public water systems is very much lower than the UCMR 1 data set indicates. This more recent data demonstrates that the UCMR 1 perchlorate data is inaccurate and biased.

A. The UCMR 1 Data Does Not Comply with Data Quality Guidelines Because it was Not Collected By Accepted Methods

The regulatory determination for perchlorate was based on the UCMR 1 data set. However, as shown below, the UCMR 1 data for perchlorate was unreliable, because a significant portion of it was collected contrary to the methodology required by the UCMR regulations. Because the UCMR 1 data was unreliable, it should not have formed the basis for the perchlorate regulatory determination. Instead, EPA should have conducted the necessary research to locate or develop a reliable set of data upon which to base the regulatory determination.

The UCMR regulations prescribe the accepted method of collecting occurrence data—the data must be collected at the point the water enters the distribution system—i.e., ***after*** the water has passed through any treatment or blending facilities operated by the relevant water system.

According to the UCMR regulations, samples for perchlorate were to be collected at the entry point to the distribution system after treatment, representing each non-emergency water source in routine use during the twelve-month period of monitoring.[1] 40 CFR § 141.40(a) & Table 1; 64 Fed. Reg. 50612, 50614. More specifically:

> The sampling location for chemical contaminants ***must be*** the entry point to the distribution system or the compliance monitoring point specified by the State or EPA under 40 CFR 141.24(f)(1), (2), and (3). If the compliance monitoring point as specified by the State is for source (raw) water and any of the contaminants in paragraph (a)(3) of this section [the twelve UCMR 1 listed contaminants, which includes perchlorate] are

[1] According to the UCMR 1 regulations, assessment monitoring was to be conducted for twelve contaminants, including perchlorate, by all 2,774 PWSs serving more than 10,000 persons, and by a representative sample of approximately 800 small PWSs serving 10,000 or fewer persons. 64 Fed. Reg. 50561. Assessment monitoring was to be conducted by each PWS over a 12-month period between 2001 and 2003. *Id.* As it turned out, some sampling was conducted after 2003, and the number of systems sampled differed slightly from that set forth in the regulations. 76 Fed. Reg. 7764.

> detected, then you [the public water system] must also sample at the entry point to the distribution system at the frequency indicated in paragraph (a)(5)(ii)(B) of this section with the following exception: If the State or EPA determines that sampling at the entry point to the distribution system is unnecessary because no treatment was instituted between source water and the distribution system that would affect the measurement of the contaminants listed in paragraph (a)(3) of this section, then you do not have to sample at the entry point to the distribution system.

40 CFR § 141.40(a)(5)(ii)(C); 64 Fed. Reg. 50617 (emphasis added). In other words, at locations where contaminants are present, sampling ***must be*** conducted at the point of entry to the distribution system. The only exception is where EPA or the State determines that there is a "pass-through" situation—where the contaminant concentration would be the same at the sample collection point and at the entry point into the water distribution system.

In contrast to these requirements, 31 percent of UCMR 1 samples were not collected at the entry point into the distribution system. Instead, they were collected from untreated source water. Brandhuber *et al.*, *A review of perchlorate occurrence in public drinking water systems*, AWWA Journal (Nov. 2009) at 67 (Exhibit A). The review conducted by Brandhuber *et al.* demonstrates that the UCMR 1 data was not collected by "accepted methods," "best available methods," or "sound research methods."

Data that is not collected in accordance with accepted methods is not reliable. The purpose of a sampling methodology is to control data collection so results are reproducible and reflect actual conditions. In the preamble to the final UCMR 1 regulation, EPA stated that specifying a sampling point "will ensure a nationally consistent data set and will provide consistent data for exposure assessment." 64 Fed. Reg. 50571. In the case of perchlorate, 31 percent of the samples were collected from the incorrect location and are thus not consistent with the remainder of the data. This does not "provide consistent data for exposure assessment."

As one might expect, perchlorate was detected with greater frequency in samples collected from untreated source water than it was in water collected at the entry point to the distribution systems. In fact, perchlorate was detected in 2.7 percent of samples collected from untreated source water, while perchlorate was detected in only 1.5 percent of samples collected from the entry point to the distribution system.

Intertox, Inc., *Comments in Response to EPA Notice* (Oct. 8, 2009) at 24 (Exhibit B). In other words, perchlorate was detected almost twice as often in untreated source water than it was at the point of entry into the water distribution systems. **This is a strong indication that the collection of a significant portion of the UCMR 1 samples from raw, untreated water sources rendered the UCMR 1 data set unreliable.**

B. The UCMR 1 Data Does Not Comply with Data Quality Guidelines Because it is not Representative of Current Conditions

More accurate and reliable data on perchlorate occurrence is available—and was available at the time of the regulatory determination—from public water systems in California than what EPA used to make its determination.

Most of the water sources that the UCMR 1 data indicated were impacted by perchlorate are located in California. More recent data from California public water systems demonstrates that the actual occurrence of perchlorate at the time of the regulatory determination is very much lower than indicated by the UCMR 1 data.

In its regulatory determination for perchlorate EPA stated that, based on UCMR 1 data, 16.6 million people (high end estimate) were served by public water systems with at least one detection of perchlorate above 4 ug/L and that 11.8 million people (high end estimate) were served by systems with at least one detection above 6 ug/L. 76 Fed. Reg. 7765. (The central value estimates of the population served by water above 4 ug/L was 5.1 million; and the central value estimate served by water above 6 ug/L was 3.0 million).[2] *Id.*

Malcolm Pirnie, Inc. consolidated the UCMR 1 data upon which EPA relied in making its regulatory determination. Malcolm Pirnie, *National Cost Implications of a Potential Perchlorate Regulation* (AWWA July 2008) at Appendix A (Exhibit C). According to Malcolm Pirnie, a total of 189 water sources had at least one sample of perchlorate above 6 ug/L. *Id.* Of these, 112 were located in California and 77 were located in other states. *Id.* Using EPA's methodology for calculating high end estimates, along with population data from EPA's Safe Drinking Water Information System (SDWIS) and EPA's UCMR 1 database, it can be determined that of the 11.8

[2] The high end estimate was derived by adding the entire population served by all public water systems in which at least one sample was found to contain perchlorate above the threshold. 76 Fed. Reg. 7765. The central value estimate was developed by assuming that the population served by the public water system was equally distributed among all entry points to the distribution system, and adding together only that proportion of the population served by those entry points that had at least one perchlorate sample above the threshold. *Id.*

million people served by public water systems with at least one detection above 6 ug/L, at least 4.2 million resided in California. *See,* Worksheet (Exhibit D).

Recent perchlorate occurrence data is available for all public water systems in California. Each quarter, the California Department of Public Health (CDPH) submits data to EPA's Safe Drinking Water Information System (SDWIS). CDPH, *Annual Compliance Report* (2009) (Exhibit E). The data submitted includes data regarding violations of maximum contaminant levels (MCLs). In California, a state MCL of 6 ug/L has been adopted for perchlorate. Public water systems in California are required to report perchlorate MCL violations to CDPH and, in turn, CDPH provides EPA with its annual compliance report, which includes data on MCL violations. *Id.* The 2009 Annual Compliance Report is the most recent annual report that has been made publicly available by CDPH. The perchlorate data collected by public water systems in California provides a more recent, accurate, reliable and complete data set for assessing perchlorate occurrence in California than the UCMR 1 dataset.[3]

CDPH's 2009 Annual Compliance Report shows that only nine public water systems in California exceed the state MCL of 6 ug/L for perchlorate. CDPH, *Annual Compliance Report* (2009) at Appendix C (Exhibit E). All of these systems were very small systems, and the total population served by these systems is 776 people. *Id.*

Thus, the *actual* population in California that is served by public water systems with at least one detection of perchlorate above 6 ug/L, according to the most recently available CDPH data, is 776 people. **This contrasts sharply with the estimate, based on UCMR 1 data, that 4.2 million people (high end estimate) in California are served by water systems with at least one detection above 6 ug/L**. The UCMR 1 data, which EPA published in its regulatory determination and upon which EPA relied in making its determination to regulate perchlorate, therefore does not satisfy the definition of "objectivity" set forth in the OMB Guidelines.

The OMB Guidelines state that "objectivity" involves a focus on ensuring accurate, reliable, and unbiased information. OMB Guidelines § V.3.b; 67 Fed. Reg. 8459. The estimate that 4.2 million people in California are served by water systems with at least one detection above 6 ug/L—an estimate that overstates the actual

[3] Because most of the California data is provided in relation to the state's 6 ug/L MCL, the best point of comparison between current California occurrence data and the old UCMR 1 data is at the 6 ug/L level. Nonetheless, helpful comparisons can also be made at most of the other levels EPA has referenced (e.g., 9, 14, 19 and 23 ug/L).

number of persons exposed to perchlorate by a factor of more than 5,000—is clearly inaccurate and biased. The actual number of people in California served water containing perchlorate above 6 ug/L was readily ascertainable at the time the regulatory determination for perchlorate was published in the Federal Register.

Thus, while it is clear the UCMR 1 occurrence data upon which EPA relied does not meet the requirements of the OMB Guidelines, what is not clear is why EPA elected to rely upon the UCMR 1 data instead of more recent readily available data.

Several events transpired since the collection of UCMR 1 data that also should have put EPA on notice that the occurrence of perchlorate was significantly less at the time it issued its regulatory determination than it was at the time of the UCMR 1 sampling. These events included:

- Several states adopted advisory or regulatory levels for perchlorate before the regulatory determination was made, including Arizona, California, Maryland, Massachusetts, Nevada, New Mexico, New York and Texas. EPA, *State Perchlorate Advisory Levels* (Apr. 20, 2005) (Exhibit F).

- Levels of perchlorate in the Colorado River, which is the source of water for approximately 20 million people in the southwest, declined significantly in the interim due to remediation efforts in Nevada. According to the Nevada Division of Environmental Protection, perchlorate concentrations declined from 9.7 ppb in June 1999 to 1.8 ppb in May 2008 (Exhibit G). Nevada DEP, *Southern Nevada Perchlorate Cleanup Project*

These events, which were well known, should have alerted EPA to the fact that the UCMR 1 perchlorate occurrence data collected between 2001 and 2003 was no longer an accurate measure of perchlorate occurrence at the time the regulatory determination was made in 2011. The systemic problem with the California occurrence data undermines the validity of the entire UCMR 1 data set because there were more detections of perchlorate in the UCMR 1 data set in California than in all other states combined.

Moreover, the problems with the UCMR 1 data set are not limited to California—there are data quality problems outside of California as well:

- During UCMR 1 sampling, the Manatee County, Florida water system had one sample that reported a concentration of 21.0 ug/L. Malcolm Pirnie, *National Cost*

Implications of a Potential Perchlorate Regulation, at 28 & Appendix A (Exhibit C). Manatee County reported that this one sample was attributable to analytical errors. *Id.* No perchlorate has been detected in water delivered by Manatee County outside of this one false positive. *Id.* The Manatee County water system serves 447,382 people, according to EPA's SDWIS database. It thus appears that 447,000 people that were counted as being exposed to perchlorate at levels above 4, 6, 9, 14 and 19 ug/L in the regulatory determination actually were not exposed above those levels.

- The UCMR 1 data indicates the City of Henderson, Nevada delivered water with concentrations of perchlorate up to 20 ug/L. Malcolm Pirnie at Appendix A. However, in its most recent publicly available consumer confidence report, the City of Henderson reports that it does not deliver water above 5.9 ug/L. City of Henderson, Water Quality Report (2008) (Exhibit H). This decline is undoubtedly due to the declining concentrations of perchlorate in the Colorado River, which is the source of Henderson's drinking water. The City of Henderson water system serves 246,000 people, according to EPA's SDWIS database. It thus appears that an additional 246,000 people that were counted as being exposed to perchlorate at levels above 6, 9, 14 and 19 ug/L in the regulatory determination actually were not exposed above those levels.

- The UCMR 1 data indicates the City of Midland, Texas delivered water with concentrations of perchlorate up to 7.9 ug/L. Malcolm Pirnie at 29 & Appendix A (Exhibit C). At the time the UCMR 1 data was collected, Midland was recharging a largely dry well field with water from a more distant source during the winter, and then pumping the well field to satisfy peak summer demand. *Id.* That practice, which caused perchlorate to enter the City's water supply, has since been discontinued and there is currently no detectible perchlorate in the Midland system. *Id.* The City of Midland water system serves 111,147 people, according to EPA. It thus appears that 111,000 people that were counted as being exposed to perchlorate at levels above 4 and 6 ug/L in the regulatory determination actually were not exposed above those levels.

- The UCMR 1 data indicates the City of High Point, North Carolina delivered water with concentrations up to 13.8 ug/L, based on one sample result; all other samples collected in the High Point system did not detect perchlorate. Malcolm Pirnie at 28 & Appendix A (Exhibit C). The laboratory that analyzed this sample has since confirmed the detection was a false positive. *Id.* Thus, there is and was no detectible perchlorate in the City of High Point water system. The City of High Point water system serves 104,000 people, according to EPA. It thus appears that an additional 104,000 people that were counted as being exposed to perchlorate at levels above 4, 6, and 9 ug/L in the UCMR 1 dataset actually were not exposed above those levels.

These four drinking water systems, which are discussed in the Malcolm Pirnie report, serve approximately 900,000 people. The UCMR 1 database reports that all four of these systems served water containing perchlorate at concentrations above 6 ug/L. However, the investigations conducted by Malcolm Pirnie establish that none of the 900,000 people served by these four systems are being provided water containing perchlorate above 6 ug/L.

Malcolm Pirnie did not conduct a comprehensive analysis of which public water systems that the UCMR 1 database reported as purveying water containing perchlorate currently purvey lower concentrations of perchlorate—or no perchlorate at all. Malcolm Pirnie only examined a very small number of large water systems to better estimate the nationwide costs of complying with a perchlorate drinking water regulation. Malcolm Pirnie at 26-29. Just in the course of its cost estimating work, Malcolm Pirnie uncovered these substantial inaccuracies in the UCMR 1 database. It is unknown what would be revealed by a more thorough review of the 160 public water systems that the UCMR 1 data set purports to show contain perchlorate.

Brandhuber *et al.* attempted to contact all 160 public water systems the UCMR 1 data set indicated purveyed drinking water containing detectible levels of perchlorate. Brandhuber *et al.* at 69-70. Key findings of this brief telephone survey were as follows: (a) 70 of the 160 system operators responded to the survey; (b) 12 systems reported that their drinking water did not contain perchlorate; (c) 13 systems have taken a total of 32 contaminated sources off-line; and (d) 9 systems were blending contaminated sources with other water. These actions would have decreased or eliminated perchlorate contamination in a significant fraction of the 160 affected public water systems.

Based on the above, it is likely that the perchlorate occurrence numbers that EPA published for other exposure levels (i.e., 4, 9, 14, 19, and 23 ug/L) are also inaccurate and biased. This conclusion is supported by the following:

- As mentioned above, several states adopted advisory or regulatory levels for perchlorate, including Arizona, California, Maryland, Massachusetts, Nevada, New Mexico, New York and Texas. EPA, *State Perchlorate Advisory Levels* (Apr. 20, 2005)

(Exhibit E). The adoptions of these levels would have reduced perchlorate concentrations in public water systems.

- Levels of perchlorate in the Colorado River, which is the source of water for approximately 20 million people in the southwest, have been declining for over a decade. Nevada DEP, *Southern Nevada Perchlorate Cleanup Project* (Exhibit F). The declining concentrations in the Colorado River also would have tended to reduce perchlorate concentrations in the many public water systems that use water from the Colorado River.

- In its regulatory determination, EPA stated 1.6 million people (high end estimate) were exposed to drinking water above 19 ug/L. Data from UCMR 1 purports to show that the following six California cities purveyed drinking water above 19 ug/L: Chino, La Verne, Pasadena, Redlands, Rialto and Riverside. The combined total population served by these water systems is 683,782, according to EPA's Safe Drinking Water Information System (SDWIS). Malcolm Pirnie shows UCMR 1 also included Manatee County and High Point as water systems purveying water above 19 ug/L, even though those systems did not actually purvey water containing perchlorate. The combined population served by these two water systems is 693,382, according to EPA's SDWIS database. CDPH and Malcolm Pirnie have shown that none of these water systems is actually purveying water above 19 ug/L. Combined, these eight water systems serve 1.38 million people.

Assuming no other errors, a more accurate high end estimate of the number of people exposed to perchlorate above 19 ug/L would be 220,000 (1.6 million minus 1.38 million). This contrasts sharply with the 1.6 million figure published by EPA in the Federal Register and relied upon in making the regulatory determination.

In sum, the UCMR 1 dataset is outdated, inaccurate, unreliable and very significantly biased (to the high side). As a result, the data set does not qualify as objective data as mandated by the IQA. Because the UCMR 1 data was not objective, it should not have formed the basis for the perchlorate regulatory determination. EPA should instead have researched and collected accurate, reliable and unbiased data. Failing that, EPA's regulatory determination on perchlorate cannot stand.

4. <u>Recommendation of Corrective Action</u>

The Chamber recommends the following corrective actions:

- Due to the very serious data quality errors in the UCMR 1 data set, EPA should publish in the Federal Register a notice retracting the data that appears in the perchlorate regulatory determination at 76 Fed. Reg. 7764-65;

- EPA should withdraw the regulatory determination itself, as there are no accurate, reliable or unbiased data to support it; and

- EPA should re-analyze the number of persons exposed to perchlorate in public water systems with: (1) data collected more recently than the UCMR 1 data; (2) data collected in accordance with accepted methods; and (3) data that is accurate, reliable and unbiased.

5. Effect of the Error

In order for EPA to regulate any substance under the SDWA, the Administrator must make three basic determinations. One of those determinations is that "the contamination is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern."

The principal effect of the errors in the UCMR 1 data set, with respect to perchlorate, is that EPA—relying on the UCMR 1 data set—made a determination to regulate perchlorate. It is clear, based on the most recent data from California public water systems, and the information brought forward by Malcolm Pirnie, that perchlorate likely does ***not*** occur with a frequency and at levels of public health concern in public water systems. It appears that current, reliable, accurate and unbiased data was available to EPA at the time it made its regulatory determination for perchlorate. If EPA had relied on that data, EPA would likely have made a determination ***not*** to regulate perchlorate.

Because EPA's determination to regulate perchlorate in drinking water is not based on current, accurate, complete, reliable and unbiased data, the Chamber is entitled to submit this stand-alone RFC. Pursuant to EPA Guidelines, the Chamber requests within 90 days the correction sought by this RFC. If EPA requires more than 90 calendar days, please provide the Chamber notice that more time is required, an explanation, and an estimated decision date. You may reach me at (202) 463-5457 or wkovacs@uschamber.com.

Sincerely,

William L. Kovacs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 28 2013

OFFICE OF WATER

William L. Kovacs
Senior Vice President, Environment, Technology & Regulatory Affairs
U.S. Chamber of Commerce
1615 H Street, NW
Washington, DC 20062

Dear Mr. Kovacs:

This is the response to your September 18, 2012, Information Quality Guidelines (IQG) Request for Correction (RFC 12004)[1]. In this letter, you requested correction of information developed and relied upon by the Environmental Protection Agency to support its determination to regulate perchlorate under the Safe Drinking Water Act (SDWA) and that the EPA withdraws the regulatory determination. The EPA's determination to regulate perchlorate is an interim step in the process that leads towards a final drinking water standard. Because the regulatory determination is not the end of a decision process and because the issues you raised with regard to the occurrence data also are integral to the development of the proposed drinking water standard for perchlorate, the EPA has chosen to use a parallel process to address several of the data issues that you have raised[2]. Specifically, the EPA will further evaluate available information on the occurrence of perchlorate in public water systems, including data provided in your RfC, to inform the Agency's Health Risk Reduction and Cost Analysis (HRRCA) for the proposed rule. We will reassess the first Unregulated Contaminant Monitoring Rule (UCMR1) data and more recent perchlorate occurrence studies (such as those from California Department of Public Health to which you refer) as part of this analysis. In that context, the EPA will carefully consider your comments and will provide an explanation of how we addressed these issues as a part of the proposed rule. The EPA will make this evaluation of the occurrence of perchlorate in public water systems available for review and comment at the time we propose the National Primary Drinking Water Regulation for perchlorate. You will have an opportunity to review and comment upon the EPA's updated analysis at that time.

The EPA is, however, responding to one aspect of the RfC here. Specifically, your letter suggests that source water monitoring data under the UCMR 1 do not comply with data quality guidelines because they were not collected by accepted methods. UCMR1 allows alternative source water sampling points if the State uses source water monitoring as a more stringent monitoring requirement (64 FR 50570). Notwithstanding the fact that some public water systems with source-water positives did not also collect samples at the entry point to the distribution system, as provided for in UCMR1, the EPA believes that

[1] RFC 12004, September 2012 <http://epa.gov/quality/informationguidelines/documents/12004.pdf>
[2] *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (October 2002); Section 8.5 (page 32) <http://epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf>

the source water results serve as an indicator of likely perchlorate occurrence in drinking water. Furthermore, the OMB's Government Wide Information Quality Guidelines emphasize that the quality of information should be commensurate with the use to which the information will be put[3]. The EPA continues to conclude that the data were appropriate for use in the context of the regulatory determination for perchlorate. If you are not satisfied with this response relating to the appropriateness of the quality of the UCMR 1 data addressed in the prior paragraph, you may submit a Request for Reconsideration (RFR). The EPA requests that any such RFR be submitted within 90 days of the date of the EPA's response. If you choose to submit an RFR, please send a written request to the EPA Information Quality Guidelines Processing Staff via mail (Information Quality Guidelines Processing Staff, Mail Code 2811R, U.S. EPA, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460); electronic mail, quality@epa.gov; or fax, (202) 565-2441. Additional information about how to submit a RFR can be found on the EPA IQG website (www.epa.gov/quality/informationguidelines).

Sincerely,

Nancy K. Stoner
Acting Assistant Administrator

cc: Malcolm D. Jackson, Assistant Administrator and Chief Information Officer, Office of Environmental Information

[3] *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (October 2002); Section 1 (page 3) <http://epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf>

CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

WILLIAM L. KOVACS
SENIOR VICE PRESIDENT
ENVIRONMENT, TECHNOLOGY &
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May 28, 2013

VIA ELECTRONIC FILING

Information Quality Guidelines Staff (Mail Code 2811R)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
quality@epa.gov

Re: Request for Reconsideration of Information Quality Act Request for Correction Regarding "Drinking Water: Regulatory Determination on Perchlorate" (RFC 12004)

On September 18, 2012, the U.S. Chamber of Commerce ("Chamber") submitted a Request for Correction ("RFC") under the Information Quality Act ("IQA"), asking EPA to correct information it published in the Federal Register regarding perchlorate occurrence in drinking water. 76 Fed. Reg. 7762 (Feb. 11, 2011). The information was not objective, within the meaning of the IQA, because it contained: (1) outdated information when more recent information was readily available; (2) information collected in violation of the directly applicable regulations; and (3) numerous outright data errors. EPA relied upon this information in making its determination to regulate perchlorate under the Safe Drinking Water Act.

On February 28, 2013, EPA responded to the Chamber's RFC by denying the RFC (in part) and stating that EPA would address other issues raised in the RFC when it publishes its proposed perchlorate drinking water rule. The RFC was assigned RFC #12004 and is attached as Exhibit 1. EPA's response to the RFC is attached as Exhibit 2.

As further discussed below, the information EPA published regarding perchlorate occurrence was based on an approximately ten-year old data set. More recent—and much more accurate—data was readily available at the time EPA published its information regarding perchlorate occurrence in the Federal Register. Further, 31 percent of the data in the data set was collected in violation of the regulations established for the collection of occurrence data under the Safe Drinking Water Act (i.e., the regulations governing collection of the specific data in question). Finally, the data has been found to contain numerous additional errors, including the reporting of false positive detections of perchlorate.

EPA did not substantively respond to the majority of the issues raised in the Chamber's RFC, stating that it would instead "use a parallel process to address several of the data issues." It violates the letter and the spirit of the IQA to use data that is not objective to initiate a significant regulatory process—a process that likely would not have been initiated in the first place if objective data had been used. The IQA requires that EPA correct the information it disseminated rather than continue using it.

EPA denied the Chamber's request that EPA correct information based on a data set collected in violation of its own regulations. EPA's regulations governing collection of contaminant occurrence data identify the specific location from which that data must be collected. EPA acknowledged that the data was not collected from the required location, but claimed that its violation of its own regulations is permissible under general guidelines issued by the Office of Management and Budget ("OMB"). This "close enough for horseshoes" response is lacking. EPA is required by law to follow its own regulations, and it cannot point to guidelines on a general topic from a different agency to justify violation of its own regulations that are directly applicable.

The Chamber seeks reconsideration of EPA's refusal to correct the information it published in the Federal Register and upon which it relied in making its determination to regulate perchlorate. The published information does not comply with the IQA[1] as implemented under OMB guidelines[2] and EPA guidelines.[3] EPA

[1] Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, P.L. 106-554; 44 U.S.C. §3516 (notes).

[2] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452 (Feb. 22, 2002) ("OMB Guidelines").

[3] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-2008 (October 2002) ("EPA Guidelines").

must correct the deficient information. Correction of the deficient information may result in reconsideration of the regulatory determination on perchlorate. However, that is the entire purpose of the IQA—to correct erroneous information so that regulatory decisions are based upon a sound scientific foundation. Any other outcome would result in an inefficient use of time and resources by EPA and all other stakeholders involved in the perchlorate rulemaking. Rather than spending resources on a regulatory process that is founded upon data that is not objective, EPA should correct the data.

I. Requester Identity and Information

The United States Chamber of Commerce is the world's largest business federation, representing the interests of more than three million businesses and organizations of every size, sector, and region. The Chamber's broad membership base includes large and small companies—more than 96 percent of Chamber members are small businesses with 100 employees or fewer—trade associations, and state and local chambers of commerce. The Chamber has member companies engaged in the use and manufacture of products containing perchlorate. Other Chamber members depend on water supplies delivered by water supply systems of all sizes. Many of these companies will be directly affected by EPA's regulatory determination, guidance, and other actions that utilize the erroneous information the RFC seeks to correct. And virtually every Chamber member would be subject to increased costs if higher prices resulted from unnecessary new rules.

Pursuant to the IQA, the Chamber is an affected person that seeks to obtain reconsideration of EPA's refusal of its request for correction of information maintained and disseminated by the agency that does not comply with OMB and EPA Guidelines. The Chamber's main point of contact for this RFC shall be:

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II. <u>Background</u>

A. <u>History of EPA's Decision</u>

On February 11, 2011, EPA published information regarding the occurrence of perchlorate in public water systems in the Federal Register. 76 Fed. Reg. 7762. Based on that information, EPA made a determination to regulate perchlorate under the Safe Drinking Water Act. *Id.* In making its determination, EPA found that perchlorate was present in public water systems at a frequency and at levels of public health concern. The information EPA relied upon was based on data collected under the first Unregulated Contaminant Monitoring Rule (UCMR 1). The UCMR 1 data provided information from 3,865 public water systems during the 2001 to 2005 time period. 76 Fed. Reg. 7764. According to EPA, the UCMR 1 data showed that as many as 11.8 million people were served by a public water system that had at least one sample with perchlorate at or above the detection limit of 4 ug/l (parts per billion). On that basis, EPA found that there was a "substantial likelihood" that "perchlorate will occur with a frequency and at levels of public health concern." 76 Fed. Reg. 7765.

B. <u>The Chamber's RFC</u>

The Chamber identified significant data quality issues in the perchlorate occurrence information EPA published in the Federal Register and which formed the basis for EPA's regulatory decision. On September 18, 2012, the Chamber lodged a Request for Correction with EPA (RFC #12004). The Chamber's RFC, attached as Exhibit 1, raised three basic issues:

(1) Nearly one-third of the UCMR 1 data, upon which the information published in the Federal Register was based, was not collected in conformance with EPA regulations governing the collection of perchlorate occurrence data. Instead of being collected at the point of entry into water distribution system piping, and after any pre-existing blending or treatment (thus reflecting water actually served to customers), 31 percent of the data was collected from raw water supplies.

(2) The UCMR 1 data was approximately ten years old and was significantly out-of-date. More recent data was readily available at the time EPA made its regulatory determination on perchlorate but, for reasons unknown, EPA did not evaluate this more recent data, which showed significantly less perchlorate occurrence in public water systems. Had EPA examined the more recent data, it would have discovered, for example, that only about

776 residents of California were served by water systems with perchlorate detections above the state MCL of 6 ug/l and not the 3 million to 11.8 million indicated by the obsolete data set upon which EPA did rely. *See* 76 Fed. Reg. 7765 & Table 2.

(3) The UCMR 1 data set included data based on erroneous laboratory reports and discontinued local water purveying practices. For example, Manatee County, Florida, and High Point, North Carolina reported one-time detections of perchlorate that were later determined to be the result of laboratory errors. In addition, Midland, Texas, and Henderson, Nevada, changed water purveying practices, substantially reducing or eliminating the presence of perchlorate in their drinking water systems. The information EPA published in the Federal Register incorporated uncorrected data based on these false positives and obsolete water purveying practices.

In brief, EPA disseminated information based on data that was out-of-date, improperly collected, and compromised by errors. EPA relied on this same information in deciding to regulate perchlorate. The Chamber requested that EPA publish a notice in the Federal Register retracting the erroneous information, and re-assess whether, based on the actual occurrence of perchlorate in public water supplies, regulation of perchlorate would be mandated by the Safe Drinking Water Act.

C. <u>EPA's Response to the RFC</u>

On February 28, 2013, EPA responded to the Chamber's RFC. EPA did not directly address the Chamber's three recommendations for corrective action: (1) that EPA publish a notice retracting the information on perchlorate occurrence published in the Federal Register; (2) that EPA withdraw the regulatory determination for perchlorate because there is no objective information to support it; and (3) that EPA analyze and publish objective information on the occurrence of perchlorate in public water systems.

However, it is clear from context that EPA does not intend to publish a notice retracting the information on perchlorate occurrence it published in the Federal Register or withdraw the regulatory determination for perchlorate. Instead, EPA stated that it would "use a parallel process to address several of the data issues that [the Chamber] raised." EPA stated that it would further evaluate information on the occurrence of perchlorate to inform its health risk reduction and cost analysis ("HRRCA"). EPA also stated that it would reassess data from the UCMR 1 data set and more recent perchlorate occurrence data as part of that analysis. Finally, EPA stated that it would make its evaluation of perchlorate occurrence in public water systems available for review and comment at the time it proposes its drinking water rule for perchlorate.

In its February 28, 2013 response EPA did respond "to one aspect of the RFC." In particular, EPA responded to the Chamber's position that occurrence data collected in violation of the UCMR 1 regulations cannot be considered to have been collected by "accepted methods" and is therefore not objective. In its response, EPA stated that notwithstanding that "some public water systems" did not collect samples "at the entry point to the distribution system, as provided for in UCMR1," data collected from raw water "serve as an indicator of likely perchlorate occurrence in drinking water." EPA referenced the OMB Guidelines for the proposition that "the quality of the data should be commensurate with the use to which the data will be put." EPA then concluded that data collected in raw water "were appropriate for use in the context of the regulatory determination."

III. Explanation of Disagreement with EPA's Response to RFC

A. EPA Must Comply With Its Own Specific Regulations Governing Data Collection

As pointed out in the Chamber's RFC, EPA's own regulations specifically require that UCMR monitoring data must measure what is actually entering the drinking water distribution system. That is, the data must reflect the water that is actually being sent to customers rather than the raw water received before blending or treatment. As the RFC explained, the UCMR clearly stated that the "sampling location ***must be*** the entry point to the distribution system," subject only to certain exceptions not applicable here. *See* 40 C.F.R. § 141.40(a)(5)(ii)(C); 64 Fed. Reg. 50617 (emphasis added).

EPA does not contest this point or suggest that the data was collected in conformance with these regulatory requirements. Rather, EPA points to general OMB guidance to excuse its failure to comply with its own regulations and urges that the OMB guidance allows EPA to rely on lower quality information. This represents a fundamental misunderstanding of both the OMB guidelines and the relevant administrative law. First, the OMB guidelines "recognize that some government information may need to meet higher or more specific information quality standards," and expressly identify "influential scientific, financial, or statistical information" as information requiring such treatment.[4] *Id.* at 8452-53. UCMR 1 data constitutes "influential scientific information" within the meaning of the OMB guidelines. Each agency is required to "adopt specific standards of quality that are appropriate for the various categories of information they disseminate." *Id.* at 8458-59.

Here, EPA adopted specific standards of quality for UCMR 1 data. As noted above, EPA's regulations state that UCMR 1 data "***must be***" collected at the "entry point to the distribution system." 40 C.F.R. § 141.40(a)(5)(ii)(C). The regulations even list two exceptions—neither of which is applicable here. Under established interpretive rules, the expression of specific exceptions means that they are the ***only*** exceptions.[5]

EPA's choice of the entry point as the sampling location is specified in regulations promulgated following notice and comment and carries the force and effect of law. EPA's technical guidance explaining the UCMR states that the entry point to the distribution system is "the preferred sampling location for a program such as the UCMR that needs to assess human exposure through drinking water." *Technical Background Information for the Unregulated Contaminant Monitoring Regulation*, § 5.1.11 (1999). EPA's technical guidance goes on to explain that "[c]oncentrations in the raw source water may change through treatment, [and] thus sampling at the source would not necessarily provide an accurate measure." *Id.* Indeed, the technical guidance goes on to state that relying on information from the raw water source—as EPA did here—"could confound the analysis." *Id.* Further, "sampling at entry points to the distribution system after any treatment follows the existing regulatory approach for currently regulated contaminants." 64 Fed. Reg. 50571.

EPA cannot ignore its own regulations. While EPA has discretion to establish procedures and weigh evidence, it is bound by and must follow its own regulations. *See, e.g., Nader v. Bork*, 366 F. Supp. 104, 108-109 (D.D.C. 1973) ("An agency regulation has the force and effect of law, and it is binding upon the body that issues it.") As the Circuit Court for the District of Columbia has explained, an agency has

[4] There is no doubt that the sampling data from UCMR 1 is "influential scientific, financial, or statistical information." The OMB guideline defines that term to mean that "the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." *Id.* at 8460. As the very purpose of the UCMR 1 data is to determine whether certain constituents should be regulated under the Safe Drinking Water Act, it is clear that this standard is met here.

[5] *See, e.g., Ethyl Corp. v. EPA*, 51 F.3d 1053, 1061 (D.C. Cir. 1995) ("mention of one thing implies the exclusion of another thing.") The specific UCMR 1 regulations are controlling over a general data quality act guideline from OMB. *See, e.g., United States v. Lara*, 181 F.3d 183, 198 (1st Cir. 1999); *see also Diaz v. Cobb*, 435 F. Supp. 2d 1206, 1213 n.7 (S.D. Fla. 2006). It is no answer to say that the regulations and OMB guideline are not in conflict; applying a general provision in this circumstance "undermines limitations created by a more specific provision." *Varity Corp. v. Howe*, 516 U.S. 489, 511 (1996).

substantial discretion to make a given policy decision. On its way to decision, however, the agency must follow its own regulations; "it is a 'well-settled rule that an agency's failure to follow its own regulations is fatal to the deviant action." *Mine Reclamation Corp. v. F.E.R.C.*, 30 F.3d 1519, 1524 (D.C. Cir. 1994).

Here, it is clear that EPA did not follow its own regulations—even EPA does not dispute that nearly one-third of the data on which it relied was not collected in compliance with UCMR 1 regulations. Pointing to general OMB guidelines does not cure this flaw, both because EPA must follow its own regulations and because the specific UCMR 1 regulations constitute the "specific standards of quality" that are called for in the OMB guidelines. This deviation is not a technicality. As the Chamber's RFC pointed out, perchlorate was detected approximately twice as often in samples collected in raw water as in samples collected at the required location. The Chamber understands that sampling raw water is not unusual, and that raw water samples can perform a valuable screening function. But as set forth in the UCMR 1 regulations, sampling the raw water is ***not*** a substitute for evaluating the water after treatment. Rather, a detection of constituents in the raw water merely indicates the need to test the finished water to determine whether the constituent is actually present in the water served to the public. That, after all, is the purpose of the program—not to examine source water, but to determine if the public is being exposed to constituents at levels which may lead to adverse health effects. Raw water samples do not support conclusions about the quality and healthfulness of water served to the public; at most, raw water detections may point to the need for data from finished water.

The Chamber again requests that EPA correct the perchlorate occurrence data set, re-analyze whether perchlorate occurs with the required frequency in public water systems, and come to a scientifically and legally defensible conclusion. Continuing with a regulatory process founded upon a data set that was not collected in compliance with applicable regulations and that does not satisfy data quality requirements is not an efficient use of EPA's resources or the resources of the other stakeholders in the regulatory process. As the Acting Administrator recently explained to the GAO, EPA has limited resources and must deploy them wisely to best protect the public.[6]

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[6] *See* July 11 2011, letter from Bob Perciasepe to David C. Trimble, Acting Director, Natural Resources and the Environment, U.S. Government Accountability Office, as reprinted in GAO-11-347, "Environmental Protection Agency: To Better Fulfill Its Mission, EPA Needs a More Coordinated Approach to Managing Its Laboratories" (August 24, 2011).

B. EPA May Not Resolve Questions About the Data Supporting Its Decision to Set an MCL for Perchlorate In the Process of Setting the MCL.

EPA deferred comment on the remaining two issues raised by the Chamber's RFC: (1) the significant data errors discovered by an independent review of that data, and (2) the fact that EPA relied on decade-old data when more recent data was readily available. Instead of responding to the issues raised in the RFC, EPA's response indicates that it will address the remaining problems with the data as part of a "parallel process" as EPA goes about setting the MCL for perchlorate.

In its guidelines, EPA describes the situations in which it intends to respond to requests for correction by using a "parallel process." The guidelines state that:

> When EPA provides opportunities for public participation by seeking comments on information, the public comment process should address concerns about EPA's information. For example, when EPA issues a notice of proposed rulemaking supported by studies and other information described in the proposal or included in the rulemaking docket, it disseminates this information within the meaning of the Guidelines. The public may then raise issues in comments regarding the information. If a group or an individual raises a question regarding information supporting a proposed rule, EPA generally expects to treat it procedurally like a comment to the rulemaking, addressing it in the response to comments rather than through a separate response mechanism." EPA Guidelines at 32.

Here, EPA did not provide an opportunity for public participation by seeking comments on the regulatory determination for perchlorate or the perchlorate occurrence information disseminated in the Federal Register. As a result, the public did not have the opportunity to raise issues in comments regarding the perchlorate occurrence information. It is worth noting that the Safe Drinking Water Act requires that regulatory determinations and their supporting documents be made available for public comment at the time the regulatory determination is published. 42 U.S.C. § 300g-1(b)(1)(B)(iii). Notwithstanding the statutory requirement, neither the regulatory determination nor the supporting information was made available for public comment.

The information for which the Chamber seeks correction was not published in a proposed rule and was not published in a manner that allowed for public comment. *See* EPA Guidelines at 32. Quite the contrary. The information on perchlorate occurrence that was published in the Federal Register was published in a notice that did ***not*** seek or allow public comment. The Chamber and other stakeholders did not have the opportunity to comment on the information. Under its own guidelines, EPA cannot address the Chamber's RFC in a "parallel process" as if it were a public comment. The "parallel process" mechanism provided for in EPA's guidelines is inapplicable to a situation where public comment was not sought. EPA must address the Chamber's RFC by responding to it directly. This situation is made all the worse because EPA was required by law to seek public comment on the regulatory determination and its supporting information. EPA did not do so. EPA cannot avoid commentary on its regulatory determination and its supporting information by deciding to not seek public comment and then avoid an IQA petition on the information supporting its regulatory determination by suggesting that the petition is somehow akin to public comment in an on-going rulemaking.

As pointed out in the Chamber's RFC, EPA's regulatory decision was based on data that both contains documented errors and is out of date. EPA does not challenge the conclusion that there are serious problems with the data, but rather says it will address them as part of a parallel process. This puts the cart before the horse. EPA should retract the information it published in the Federal Register, which does not comport with the IQA; identify and collect information of the requisite quality; and re-visit its regulatory determination.

The perchlorate occurrence data was used to determine whether an MCL was necessary at all. It is problematic to suggest that the answer to ***whether*** to set an MCL for perchlorate can be answered in the context of deciding ***what*** the MCL should be. EPA's response appears to assume a conclusion. The Chamber has proffered evidence that: (1) less than 1,000 people in California were being exposed to perchlorate above the current California regulatory level at the time of regulatory determination instead of over 4 million indicated in the information disseminated in the Federal Register; and (2) a peer-reviewed publication that surveyed water purveyors found another 1 million false positives in the underlying data.

The agency cannot meaningfully address whether to go somewhere in the process of deciding the best route to get there. Courts have repeatedly rejected such *post hoc* rationalizations for agency action. *Southwest Airlines Co. v. Transportation Sec. Admin.*, 650 F.3d 752, 761 (D.C. Cir. 2011). EPA concedes that it may not set an MCL for perchlorate without finding that perchlorate is both frequently present in public drinking water systems and that regulation is likely to eliminate health risks. The data that it relied upon to reach those conclusions here is fundamentally flawed, and EPA must correct it.

Rather than continue down its current path, EPA should first correct the data it published in the Federal Register. Continuing down the current path in reliance on a deeply flawed data set is neither an efficient use of the agency's resources or the resources of the participating stakeholders. Proceeding with a rulemaking that is founded upon information fraught with such serious data quality problems violates the letter and spirit of the IQA. The Chamber urges EPA to formally retract the perchlorate occurrence information it published in the Federal Register.

IV. Specific Recommendation for Corrective Action

As set forth in the RFC, EPA should: (1) publish in the Federal Register a notice retracting the perchlorate occurrence information that appears in the perchlorate regulatory determination at 76 Federal Register, pages 7764-65; (2) withdraw the regulatory determination itself, as there are no accurate, reliable, or unbiased data to support it; and (3) re-analyze the number of persons exposed to perchlorate in public water systems with data of the requisite quality.

V. Conclusion

EPA's decisions gain acceptance from the public and the regulated community if they are driven by science. In adopting the Information Quality Act, Congress imposed basic data quality standards to further this end. EPA should gather reliable, accurate, and objective data, and follow that data to whatever conclusions it demands. Anything less than that violates the IQA, Safe Drinking Water Act, and established agency policy.

If EPA requires more than 90 calendar days to make a decision on this Request for Reconsideration, please provide the Chamber notice that more time is required, an explanation, and an estimated decision date. You may reach me at (202) 463-5457 or wkovacs@uschamber.com.

Sincerely,

William L. Kovacs

Option Selection for Perchlorate Final Regulatory Action

Draft - 1/7/2020

Purpose:

- Obtain a decision on the final SDWA action for perchlorate to assure meeting the consent decree deadline of June 19, 2020.

Background:

- Perchlorate is commonly used in solid rocket propellants, munitions, fireworks, airbag initiators for vehicles, matches, and signal flares.
- Perchlorate may occur naturally, particularly in arid regions such as the southwestern United States.
- Perchlorate can prevent uptake of iodide into the thyroid gland, which can affect thyroid hormone production.
- In some circumstances, changes in thyroid hormone levels in a pregnant woman may be linked to changes in the child's brain development.
- For infants, disruptions in thyroid hormone function can also impact brain development.

Proposed Rule:

- On June 26, 2019, the EPA released a notice of proposed rulemaking seeking public comment on a range of options regarding the regulation of perchlorate in public drinking water systems.
- The EPA proposed a National Primary Drinking Water Regulation (NPDWR) for perchlorate with a Maximum Contaminant Level (MCL) and Maximum Contaminant Level Goal (MCLG) of 56 micrograms per liter (μg/L).
- The proposed MCLG of 56 μg/L is based upon avoiding a 2 point IQ decrement associated with exposure during the most sensitive life stage (the fetus) within a specific segment of the population (iodine deficient pregnant women).
- The proposed regulation would require over sixty thousand public water systems to monitor for perchlorate. Proposed monitoring requirements are consistent with the current standardized monitoring framework for inorganics and allow for monitoring waivers or reduced monitoring for systems with low or no occurrence following the initial round of sampling.
- The Agency requested comment on alternative MCL and MCLG values – 18 and 90 μg/L. These alternatives are based upon avoiding 1 point and 3 point IQ decrements associated with exposure during the most sensitive life stage within a specific segment of the population.
- Based on perchlorate occurrence data, the EPA estimated that two systems would be required to take action to reduce levels below 56 μg/L, fifteen systems would be required to take action to reduce levels below 18 μg/L, and one system would be required take action to reduce levels below 90 μg/L.
- The EPA determined the benefits of the proposed rule <u>do not</u> justify the costs at the proposed or alternative MCLs.
- The Agency also requested comment on whether the EPA should withdraw the 2011 determination to regulate perchlorate.

Public Comments on Proposed Rule:

The public comment period on the perchlorate proposal ended on August 26, 2019, and EPA received a total of 1,495 comments in response to its rulemaking proposal.

<u>Mass Mailing Campaign:</u> 1,386 comments were received under a mass mailing campaign. These commenters oppose the proposed MCLG/MCL of 56 μg/L, stating that it is too high to adequately protect the health of communities.

Option Selection for Perchlorate Final Regulatory Action

Draft - 1/7/2020

Detailed Comment Letters from Organizations: 28 Comment letters addressing technical and policy issues were submitted. The overall recommendations of these comment letters on the regulatory proposal breakdown as follows.

- None support the proposed MCLG/MCL of 56 μg/L.
- None support the 90 μg/L alternative MCLG/MCL.
- Two support the 18 μg/L alternative MCLG/MCL:
  - Oregon
  - Virginia

- Fourteen support regulation at a MCLG/MCL lower than 18 μg/L:
  - Massachusetts
  - California
  - New Jersey
  - New York
  - Association of California Water Agencies
  - Metropolitan Water District of Southern California
  - The Salt River Pima-Maricopa Indian Nation
  - The Tohono O'odham Nation
  - Alaska Community Action on Toxics
  - Environmental Defense Fund
  - Environmental Protection Network
  - Environmental Working Group
  - Natural Resources Defense Council
  - American Academy of Pediatrics

- Eleven support withdrawal of the determination to regulate perchlorate:
  - South Dakota
  - U.S. Conference of Mayors & the National League of Cities (joint letter)
  - California Farm Bureau Federation
  - American Water
  - El Paso Water
  - American Chemistry Council
  - American Water Works Association
  - Association of Metropolitan Water Agencies
  - National Rural Water Association
  - Perchlorate Study Group
  - The Chlorine Institute

- One organization did not take a position regarding regulation of perchlorate:
  - Association of State Drinking Water Administrators

Individuals: Eighty-one comment letters with varied levels of complexity were submitted by individuals. These letters cover a wide array of technical and policy issues regarding the perchlorate proposal. The overall recommendations of these comment letters on the regulatory proposal breakdown as follows.

  - 6 support the 56 μg/L proposed MCLG/MCL.
  - 1 supports the 90 μg/L alternative MCLG/MCL.

- 6 support the 18 µg/L alternative MCLG/MCL.
- 23 support regulation at an MCLG/MCL lower than 18 µg/L.
- 1 supports the withdrawal of the regulatory determination.
- 44 are in general opposition and/or out of scope.

Potential Options for Decision Making:

Ex. 5 AC/AWP/DP

Option Selection for Perchlorate Final Regulatory Action

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- Ex. 5 AC/AWP/DP

- Ex. 5 AC/AWP

f

Ex. 5 AC/AWP/DP

Ex. 5 AC/AWP/DP

Ex. 5 AC/AWP/DP

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Ex. 5 AC/AWP/DP

Ex. 5 AC/AWP

Ex. 5 AC/AWP/DP

Ex. 5 AC/AWP/DP

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APPENDIX

Comparison of Annual Costs and Benefits by MCL for the Proposed Standardized Monitoring Framework (Millions; 2017$)

MCL	Cost 3% Discount	Benefit 3% Discount[a]	Cost 7% Discount	Benefit 7% Discount[a]
4 μg/L	$58.11	$6.85 ($1.50-$12.20)	$61.84	$1.15 ($0.25-$2.04)
11 μg/L	$23.64	$4.85 ($1.06-$8.64)	$24.89	$0.81 ($0.18-$1.45)
18 μg/L[b]	$16.95	$3.68 ($0.80-$6.56)	$17.96	$0.62 ($0.14 -$1.11)
56 μg/L[c]	$9.67	$2.00 ($0.44 -$3.57)	$10.28	$0.34 ($0.07- $0.60)
90 μg/L[b]	$9.51	$1.83 ($0.40-$3.26)	$10.10	$0.31 ($0.07-$0.55)
175 μg/L	$9.44	$1.48 ($0.32-$2.63)	$10.02	$0.25 ($0.05-$0.44)
420 μg/L[d]	$9.02	$0.00 ($0.00-$0.00)	$9.58	$0.00 ($0.00-$0.00)

Notes:

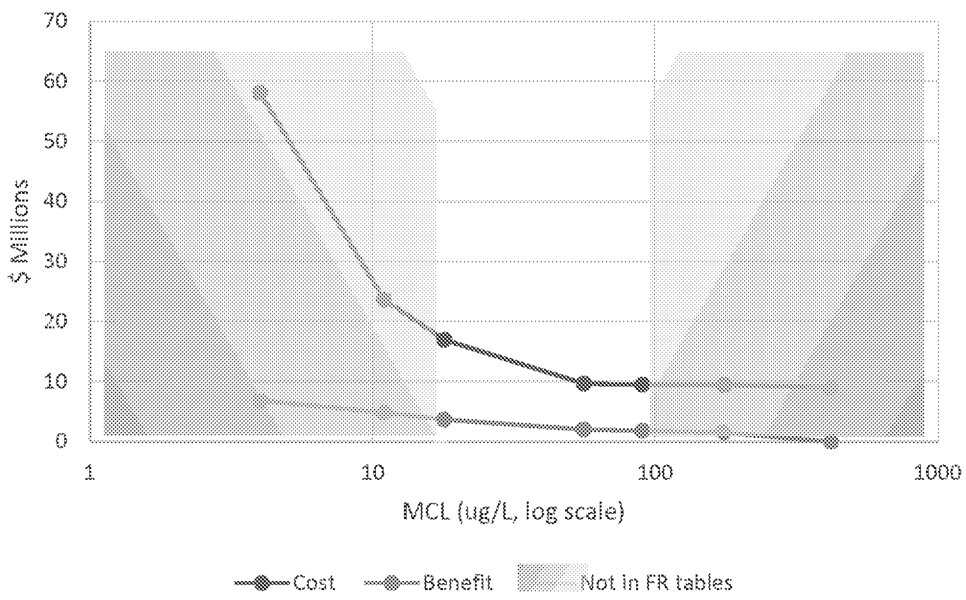
a. First benefit value reported is based on the central estimate of the gamma coefficient in: $\Delta IQ=(\gamma\times\ln(fT4_{rule}))-(\gamma\times\ln(fT4_{baseline}))$. The benefit range in parenthesis is based on the upper and lower bounds of the 95[TH] confidence interval around the gamma estimate.

b. EPA took comment on alternative MCLG/MCL of 18 and 90 μg/L.

c. EPA proposed an MCL of 56 μg/L

d. The highest perchlorate concentration observed in UCMR 1 is one sample at 420 ppb.

Chart for 3% Discount Rate Cost and Benefit Values



MCL (μg/L)	4	11	18	56	90	175	420
IQ loss	0.5	0.75	1	2	3	5	8.2

Message

From: Aguirre, Janita [Aguirre.Janita@epa.gov]
Sent: 5/21/2020 7:09:42 PM
To: Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]
CC: Ross, David P [ross.davidp@epa.gov]; Braschayko, Kelley [braschayko.kelley@epa.gov]
Subject: Charlotte - for review/signature - Perchlorate FRN to OP for Interagency Review
Attachments: Perchlorate Transmittal Memo AA to OP for OMB Review.pdf; EO12866_SDWA NPDWR 2040-AF28 FRN Perchlorate Rule 20200521.docx; Perchlorate Action Memo 5-19-20.docx

Importance: High

Hi Charlotte,

Please see the electronic blue folder for the Notice of Final Action on Perchlorate to go to OP to be submitted to OMB for interagency review. I spoke with Dave and he has delegated package approval/transmittal memo signature to you. When you are ready to approve, please sign the transmittal memo (attachment 1). Please let me know if you find any edits to the memo or the package. Once signed, please send it back to me, and Sandy will move it to the next step.

- For attachment 1, your e-signature in PDF will look something like this:

SHARON HAMER

Digitally signed by SHARON HAMER
Date: 2020.03.12 17:21:45 -04'00'

Attachments

1. SIGN: Transmittal memo for your signature
2. Draft Perchlorate FRN to be sent to OMB
3. Draft Action Memo (will be kept in draft until time for final FRN signature).
4. OCG Concurrence emails – see below my signature block

Thank you,
Janita

Janita Aguirre – Special Assistant to David Ross and Anna Wildeman
U.S. Environmental Protection Agency | Office of Water | Office of the Assistant Administrator
Phone: **(202) 566-1149** | Email: **aguirre.janita@epa.gov**

From: Parikh, Pooja <Parikh.Pooja@epa.gov>
Sent: Thursday, May 21, 2020 12:04 PM
To: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Cc: Wehling, Carrie <Wehling.Carrie@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Request for Concurrence - Revised Perchlorate FRN

Sam,

Per our discussion, I have reviewed the redlined version of all of the changes to the FRN since the FAR version. I confirmed that all of OGC's comments on the FAR version have been sufficiently addressed – and only had a couple of minor additional edits – please see attached (my edits are marked with comment bubbles). With these edits, the FRN is ready to move forward. Thanks.

Pooja

Pooja S. Parikh
Attorney- Advisor
U.S. Environmental Protection Agency
Office of General Counsel, Water Law Office
Phone: 202 564-0839
Email: parikh.pooja@epa.gov

From: Parikh, Pooja <Parikh.Pooja@epa.gov>
Sent: Thursday, May 07, 2020 9:52 AM
To: Evalenko, Sandy <Evalenko.Sandy@epa.gov>
Cc: Wehling, Carrie <Wehling.Carrie@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: Perchlorate FRN -- OGC concurs with comment

On behalf of the General Counsel, I am providing OGC's concurrence on the Federal Register Notice referenced in the email below, subject to the attached comments. I will be representing OGC at the FAR meeting. Please let me know if you have any questions or require additional information. Thank you.

Pooja

Pooja S. Parikh
Attorney- Advisor
U.S. Environmental Protection Agency
Office of General Counsel, Water Law Office
Phone: 202 564-0839
Email: parikh.pooja@epa.gov

Message

From: Fotouhi, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FEBAF0D56AAB43F8A9174B18218C1182-FOTOUHI, DA]
Sent: 3/14/2019 11:41:33 PM
To: O'Scannlain, Kevin S. EOP/WHO Ex. 6 Personal Privacy (PP)
CC: Leopold, Matt (OGC) [Leopold.Matt@epa.gov]
Subject: Perchlorate
Attachments: EPA DRAFT perchlorate.docx

PRIVILEGED—DELIBERATIVE—DO NOT RELEASE

Kevin:

Per our conversation yesterday, please see the attached. Let me know if you have any questions. Thank you.

Best,

David

David Fotouhi

Principal Deputy General Counsel
Office of General Counsel
U.S. Environmental Protection Agency
Tel: +1 202.564.1976
fotouhi.david@epa.gov

Message

From: Clark, Joseph R. EOP/WHO Ex. 6 Personal Privacy (PP)
Sent: 5/23/2019 3:32:35 AM
To: Leopold, Matt (OGC) [Leopold.Matt@epa.gov]
Subject: Re: FYI -- Discussion with DOJ re perchlorate proposal

That works.

Best,
Joe

Sent from my iPhone

On May 22, 2019, at 9:08 PM, Leopold, Matt (OGC) <Leopold.Matt@epa.gov> wrote:

> Can do it tomorrow at 8 am?
>
> Sent from my iPhone
>
> On May 22, 2019, at 10:31 AM, Clark, Joseph R. EOP/WHO Ex. 6 Personal Privacy (PP) wrote:
>
>> Yes, that'd be great. Just give me a ring whenever would work best for you.
>>
>> Best,
>> Joe
>>
>> Sent from my iPhone
>>
>> On May 22, 2019, at 10:14 AM, Leopold, Matt (OGC) <Leopold.Matt@epa.gov> wrote:
>>
>>> I'm slammed until after 6. Can we connect then?
>>>
>>> Sent from my iPhone
>>>
>>> On May 22, 2019, at 9:44 AM, Clark, Joseph R. EOP/WHO <Ex. 6 Personal Privacy (PP)> wrote:
>>>
>>>> I have a meeting that will end about 10:30 – would that work for you? Otherwise I can call at your convenience.
>>>>
>>>> Best,
>>>> Joe
>>>>
>>>> **From:** Leopold, Matt (OGC) <Leopold.Matt@epa.gov>
>>>> **Sent:** Wednesday, May 22, 2019 9:27 AM
>>>> **To:** Clark, Joseph R. EOP/WHO
>>>> Ex. 6 Personal Privacy (PP)
>>>> **Subject:** Re: FYI -- Discussion with DOJ re perchlorate proposal
>>>>
>>>> I'm at the EEOB for the next hour. Would you have time at 10:15?

Sent from my iPhone

On May 21, 2019, at 2:34 PM, Clark, Joseph R. EOP/WHO <Ex. 6 Personal Privacy (PP)> wrote:

Absolutely. Would sometime between 11:30 and 3 pm, or after 4:30, work?

Best,
Joe

From: Leopold, Matt (OGC) <Leopold.Matt@epa.gov>
Sent: Tuesday, May 21, 2019 2:05 PM
To: Clark, Joseph R. EOP/WHO <Ex. 6 Personal Privacy (PP)
Subject: Fwd: FYI -- Discussion with DOJ re perchlorate proposal

Joe, can we catch up about this tomorrow?

Sent from my iPhone

Begin forwarded message:

From: "Fotouhi, David" <Fotouhi.David@epa.gov>
Date: May 21, 2019 at 1:59:19 PM EDT
To: "Leopold, Matt (OGC)" <Leopold.Matt@epa.gov>, "Ross, David P" <ross.davidp@epa.gov>, "Bolen, Brittany" <bolen.brittany@epa.gov>
Subject: Fwd: FYI -- Discussion with DOJ re perchlorate proposal

Please see below.

Sent from my iPhone

Begin forwarded message:

From: "Messier,

Dawn" <Messier.Dawn@epa.gov>
Date: May 15, 2019 at 11:39:23 AM EDT
To: "Fotouhi, David" <Fotouhi.David@epa.gov>, "Burneson, Eric" <Burneson.Eric@epa.gov>
Cc: "Wehling, Carrie" <Wehling.Carrie@epa.gov>
Subject: FYI -- Discussion with DOJ re perchlorate proposal

David and Eric – Carrie and I spoke this mornin g with staff from ENRD, including reps from the law and policy section, as well as our SDNY attorneys, about the perchlorate proposal. They all had a call yesterday with the White House Counsel's office and OMB to which EPA was not invited. During that call, OMB asked DOJ whethe

Ex. 5 AC/DP

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Ex. 5 AC/DP

s.

As a result of our call, DOJ staff plan to send Jon Brightbill a suggested email to OMB

Ex. 5 AC/DP

Ex. 5 AC/DP

Ex. 5 AC/DP

Carrie feel free to chime in if I missed anything.

Dawn

Dawn Messier
U.S.E.P.A.
Office of General Counsel
Water Law Office
202-564-5517

Message

From: Leopold, Matt (OGC) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E5CDF09A3924DADA6D322C6794CC4FA-LEOPOLD, MA]
Sent: 5/22/2019 3:02:19 PM
To: Clark, Joseph R. EOP/WHO Ex. 6 Personal Privacy (PP)
BCC: Mutz, John [mutz.john@epa.gov]
Subject: RE: FYI -- Discussion with DOJ re perchlorate proposal

Okay. Will call at 6:30

Matthew Z. Leopold
General Counsel
U.S. Environmental Protection Agency
(202) 564-8040

From: Clark, Joseph R. EOP/WHO < Ex. 6 Personal Privacy (PP)
Sent: Wednesday, May 22, 2019 10:32 AM
To: Leopold, Matt (OGC) <Leopold.Matt@epa.gov>
Subject: Re: FYI -- Discussion with DOJ re perchlorate proposal

Yes, that'd be great. Just give me a ring whenever would work best for you.

Best,
Joe

Sent from my iPhone

On May 22, 2019, at 10:14 AM, Leopold, Matt (OGC) <Leopold.Matt@epa.gov> wrote:

> I'm slammed until after 6. Can we connect then?
>
> Sent from my iPhone
>
> On May 22, 2019, at 9:44 AM, Clark, Joseph R. EOP/WHO < Ex. 6 Personal Privacy (PP) wrote:
>
> > I have a meeting that will end about 10:30 – would that work for you? Otherwise I can call at your convenience.
> >
> > Best,
> > Joe
> >
> > ---
> >
> > **From:** Leopold, Matt (OGC) <Leopold.Matt@epa.gov>
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Best,
Joe

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Sent: Tuesday, May 21, 2019 2:05 PM
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Sent from my iPhone

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> **To:** "Leopold, Matt (OGC)" <Leopold.Matt@epa.gov>, "Ross, David P" <ross.davidp@epa.gov>, "Bolen, Brittany" <bolen.brittany@epa.gov>
> **Subject: Fwd: FYI -- Discussion with DOJ re perchlorate proposal**
>
> Please see below.
>
> Sent from my iPhone
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>> **From:** "Messier, Dawn" <Messier.Dawn@epa.gov>
>> **Date:** May 15, 2019 at 11:39:23 AM EDT
>> **To:** "Fotouhi, David" <Fotouhi.David@epa.gov>, "Burneson, Eric" <Burneson.Eric@epa.gov>
>> **Cc:** "Wehling, Carrie" <Wehling.Carrie@epa.gov>
>> **Subject: FYI -- Discussion with DOJ re perchlorate proposal**
>>
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>>
>> **Ex. 5 AC/AWP/DP**

Ex. 5 AC/AWP/DP

As a result of our call, DOJ staff plan to send Jon Brightbill a suggested email to OMB stating that Ex. 5 AC/AWP/DP

Ex. 5 AC/AWP/DP

Carrie feel free to chime in if I missed anything.

Dawn

Dawn Messier
U.S.E.P.A.
Office of General Counsel
Water Law Office
202-564-5517

Message

From: Bretz, Emily (USANYS) [Emily.Bretz@usdoj.gov]
Sent: 10/7/2016 4:04:06 PM
To: Carney, Matt B. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Messier, Dawn [Messier.Dawn@epa.gov]
CC: Wehling, Carrie [Wehling.Carrie@epa.gov]; Walsh, Heather V. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Perchlorate

Thanks very much, Matt

-----Original Message-----
From: Carney, Matt B. EOP/OMB [mailto: Ex. 6 Personal Privacy (PP)]
Sent: Friday, October 7, 2016 12:00 PM
To: Messier, Dawn <Messier.Dawn@epa.gov>
Cc: Bretz, Emily (USANYS) <EBretz@usa.doj.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Walsh, Heather V. EOP/OMB < Ex. 6 Personal Privacy (PP) >
Subject: RE: Perchlorate

Adding Heather Walsh from OMB.

Thanks a lot for the helpful information and background on this. OMB clears this Consent Decree.

Thanks,
Matt

-----Original Message-----
From: Messier, Dawn [mailto:Messier.Dawn@epa.gov]
Sent: Friday, October 7, 2016 11:43 AM
To: Carney, Matt B. EOP/OMB < Ex. 6 Personal Privacy (PP) >
Cc: Emily.Bretz@usdoj.gov; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: Perchlorate

Matt- could you please cc Emily and Carrie on your future emails so there's no delay due to my traveling? Thanks. Dawn

Sent from my iPhone

Message

From: Carney, Matt B. EOP/OMB Ex. 6 Personal Privacy (PP)
Sent: 10/5/2016 3:37:54 PM
To: Messier, Dawn [Messier.Dawn@epa.gov]
Subject: RE: EPA Draft Consent Decree for Review (Perchlorate)

Thanks, Dawn. We will review this as quickly as we can and I will circle back.

From: Messier, Dawn [mailto:Messier.Dawn@epa.gov]
Sent: Wednesday, October 5, 2016 11:35 AM
To: Carney, Matt B. EOP/OMB Ex. 6 Personal Privacy (PP)
Subject: Re: EPA Draft Consent Decree for Review (Perchlorate)

Vlad Doorjet, Jim Kim, Margo Schwab

Sent from my iPhone

On Oct 5, 2016, at 10:55 AM, Carney, Matt B. EOP/OMB < Ex. 6 Personal Privacy (PP) > wrote:

> Thanks, Dawn. Any insight on who in EPA has been working with OIRA on this would be helpful.
>
> Best,
> Matt
>
> **From:** Messier, Dawn [mailto:Messier.Dawn@epa.gov]
> **Sent:** Wednesday, October 5, 2016 10:54 AM
> **To:** Carney, Matt B. EOP/OMB < Ex. 6 Personal Privacy (PP)
> **Subject:** FW: EPA Draft Consent Decree for Review (Perchlorate)
>
> Dawn Messier
> U.S.E.P.A.
> Office of General Counsel
> Water Law Office
> 202-564-5517
>
> **From:** Messier, Dawn
> **Sent:** Friday, September 30, 2016 7:56 AM
> **To:** Ilona_R._Cohen@ Ex. 6 Personal Privacy (PP)
> **Cc:** Wehling, Carrie <Wehling.Carrie@epa.gov>; Neugeboren, Steven <Neugeboren.Steven@epa.gov>
> **Subject:** EPA Draft Consent Decree for Review (Perchlorate)
>
> Attached for your review is a draft consent decree. This consent decree will completely resolve claims raised in a complaint filed by the Natural Resources Defense Counsel in the Southern District of New York. *Natural Resources Defense Council v. U.S. EPA*, Case No. 16-cv-1251 (S.D.N.Y.) If OMB has questions, you can contact me (Dawn Messier, 202-564-5517) or Carrie Wehling (202-564-5492). We would like your feedback on the decree by October 4, 2016.

This agreement would effectuate the settlement of a case in which NRDC alleges that EPA has violated mandatory duties to issue proposed and final rules promulgating a maximum contaminant level goal (MCLG) and national primary drinking water regulation (NPDWR) for perchlorate under the Safe Drinking Water Act (SDWA). The consent decree would require EPA to sign a proposed rule by October 31, 2018 and a final rule by December 19, 2019. The decree also contains a non-enforceable October 18, 2017 deadline for completion of EPA's ongoing peer review process of its modeling approach for determining an MCLG for perchlorate. Settlement under the terms of this consent decree avoids significant legal risk that a court would impose a less favorable schedule than is contained in the consent decree and subject the Agency to time-consuming discovery and briefing on the issue of an appropriate schedule.

Background

SDWA sets out procedures and criteria for EPA to use in determining whether to regulate a particular contaminant in drinking water. *See* SDWA § 1412(a). EPA must make determinations whether to regulate at least 5 contaminants every 5 years and subject such determinations to public notice and comment. SDWA § 1412(b)(1)(B)(ii). Determinations to regulate must be based on three findings found in Section 1412(b)(1)(A)(i)-(iii): (1) "the contaminant may have an adverse effect on the health of persons;" (2) "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern;" and (3) "in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems."

EPA initially proposed not to regulate perchlorate in 2008, but after reviewing public comments, the Agency published a final determination to regulate perchlorate under SDWA. 76 Fed. Reg. 7762 (February 11, 2011). This determination triggered a mandatory duty to propose an MCLG and NPDWR for perchlorate by February 11, 2013. SDWA § 1412(b)(1)(E). EPA has not yet proposed an MCLG and NPDWR for perchlorate, primarily due to the Agency's efforts to follow the recommendations of EPA's Science Advisory Board (SAB). When EPA, as required by SDWA §1412(e), asked the SAB for comments on the Agency's planned approach to deriving an MCLG for perchlorate, the Board recommended the Agency change course and develop a novel biologically based dose response ("BBDR") modeling approach instead. EPA has recently initiated the peer review process for the BBDR modeling approach it has developed for use in deriving an MCLG for perchlorate.

Consent Decree

The key terms of the draft consent decree are as follows:

- **October 18, 2017:** This is the date by which the decree states that EPA "intends" to complete peer review. If EPA determines that it will not complete the external peer review process by that date, EPA shall file a status report with the court no later than

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- **December 19, 2019**: This is the date by which EPA shall sign for publication in the Federal Register a final MCLG and NPDWR for perchlorate.

Recommendation

We have recommended settlement of this matter, for several reasons. In this litigation, EPA has already conceded that it violated a mandatory duty to propose an MCLG and NPDWR for perchlorate. As the parties continue to disagree on whether the Agency also violated a mandatory duty to promulgate a final MCLG and NPDWR, this settlement allows the Agency to

Ex. 5 AC/AWP/DP

Finally, the Office of Ground Water and Drinking Water (OGWDW) has evaluated the potential resources necessary to comply with the Consent Decree. OGWDW does not believe that

Ex. 5 AC/AWP/DP

We look forward to hearing from you. Again, if you have questions, you can reach me at 202-564-5517 or Carrie Wehling at 202-564-5492.

Message

From: Carney, Matt B. EOP/OMB Ex. 6 Personal Privacy (PP)
Sent: 10/5/2016 3:07:11 PM
To: Messier, Dawn [Messier.Dawn@epa.gov]
Subject: RE: EPA Draft Consent Decree for Review (Perchlorate)

Dawn,

Could you also shoot over the complaint when you have a moment? If there any additional filings that may be helpful, that would be great as well.

Thanks,
Matt

From: Messier, Dawn [mailto:Messier.Dawn@epa.gov]
Sent: Wednesday, October 5, 2016 10:54 AM
To: Carney, Matt B. EOP/OMB Ex. 6 Personal Privacy (PP)
Subject: FW: EPA Draft Consent Decree for Review (Perchlorate)

Dawn Messier
U.S.E.P.A.
Office of General Counsel
Water Law Office
202-564-5517

From: Messier, Dawn
Sent: Friday, September 30, 2016 7:56 AM
To: Ilona R. Cohen@ Ex. 6 Personal Privacy (PP)
Cc: Wehling, Carrie <Wehling.Carrie@epa.gov>; Neugeboren, Steven <Neugeboren.Steven@epa.gov>
Subject: EPA Draft Consent Decree for Review (Perchlorate)

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Recommendation

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Finally, the Office of Ground Water and Drinking Water (OGWDW) has evaluated the potential resources necessary to comply with the Consent Decree. OGWDW does not believe that Ex. 5 AC/AWP/DP

Ex. 5 AC/AWP/DP

We look forward to hearing from you. Again, if you have questions, you can reach me at 202-564-5517 or Carrie Wehling at 202-564-5492.

Message

From: Carney, Matt B. EOP/OMB Ex. 6 Personal Privacy (PP)
Sent: 10/5/2016 2:43:53 PM
To: Messier, Dawn [Messier.Dawn@epa.gov]
CC: Walsh, Heather V. EOP/OMB Ex. 6 Personal Privacy (PP)
Subject: RE: EPA Draft Consent Decree for Review (Perchlorate)

Dawn,

Dropping Ilona and Varun and adding Heather Walsh.

Could you please pass along any of the documents you have on this? While I cannot speak for DOJ, we are happy to review and discuss with our clients.

Thanks,
Matt

Matthew B. Carney
Office of the General Counsel
Office of Management and Budget
Phone: Ex. 6 Personal Privacy (PP)
Mobile: Ex. 6 Personal Privacy (PP)

From: Messier, Dawn [mailto:Messier.Dawn@epa.gov]
Sent: Wednesday, October 5, 2016 10:10 AM
To: Cohen, Ilona R. EOP/OMB <Ex. 6 Personal Privacy (PP)
Cc: Jain, Varun M. EOP/OMB <Ex. 6 Personal Privacy (PP) Carney, Matt B. EOP/OMB <Ex. 6 Personal Privacy (PP)
Subject: RE: EPA Draft Consent Decree for Review (Perchlorate)

Hi. I am following up on the email below. May I assume that DOJ has no questions or concerns regarding this decree? Thanks. Dawn

Dawn Messier
U.S.E.P.A.
Office of General Counsel
Water Law Office
202-564-5517

From: Messier, Dawn
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Ex. 5 AC/AWP/DP

We look forward to hearing from you. Again, if you have questions, you can reach me at 202-564-5517 or Carrie Wehling at 202-564-5492.

Message

From: Wehling, Carrie [Wehling.Carrie@epa.gov]
Sent: 10/7/2016 4:22:54 PM
To: Carney, Matt B. EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Messier, Dawn [Messier.Dawn@epa.gov]; Emily.Bretz@usdoj.gov; Walsh, Heather V. EOP/OMB Ex. 6 Personal Privacy (PP)
Subject: Re: Perchlorate

Great. Thanks.

Sent from my iPhone

> On Oct 7, 2016, at 12:02 PM, Carney, Matt B. EOP/OMB Ex. 6 Personal Privacy (PP) wrote:
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>
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> Subject: Perchlorate
>
> Matt- could you please cc Emily and Carrie on your future emails so there's no delay due to my traveling? Thanks. Dawn
>
> Sent from my iPhone

Message

From: Messier, Dawn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A13A4CD15EC94FE181AA84E34AC0561A-DMESSIER]
Sent: 10/5/2016 2:56:13 PM
To: Carney, Matt B. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: EPA Draft Consent Decree for Review (Perchlorate)

I've sent an email to the program folks. Will let you know as soon as I hear.

Dawn Messier
U.S.E.P.A.
Office of General Counsel
Water Law Office
202-564-5517

From: Carney, Matt B. EOP/OMB [mailto: Ex. 6 Personal Privacy (PP)]
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Subject: EPA Draft Consent Decree for Review (Perchlorate)

Attached for your review is a draft consent decree. This consent decree will completely resolve claims raised in a complaint filed by the Natural Resources Defense Counsel in the Southern District of New York. *Natural Resources Defense Council v. U.S. EPA*, Case No. 16-cv-1251 (S.D.N.Y.) If OMB has questions, you can contact me (Dawn Messier, 202-564-5517) or Carrie Wehling (202-564-5492). We would like your feedback on the decree by October 4, 2016.

This agreement would effectuate the settlement of a case in which NRDC alleges that EPA has violated mandatory duties to issue proposed and final rules promulgating a maximum contaminant level goal (MCLG) and national primary drinking water regulation (NPDWR) for perchlorate under the Safe Drinking Water Act (SDWA). The consent decree would require EPA to sign a proposed rule by October 31, 2018 and a final rule by December 19, 2019. The decree also contains a non-enforceable October 18, 2017 deadline for completion of EPA's ongoing peer review process of its modeling approach for determining an MCLG for perchlorate. Settlement under the terms of this consent decree avoids significant legal risk that a court would impose a less favorable schedule than is contained in the consent decree and subject the Agency to time-consuming discovery and briefing on the issue of an appropriate schedule.

Background

SDWA sets out procedures and criteria for EPA to use in determining whether to regulate a particular contaminant in drinking water. *See* SDWA § 1412(a). EPA must make determinations whether to regulate at least 5 contaminants every 5 years and subject such determinations to public notice and comment. SDWA § 1412(b)(1)(B)(ii). Determinations to regulate must be based on three findings found in Section 1412(b)(1)(A)(i)-(iii): (1) "the contaminant may have an adverse effect on the health of persons;" (2) "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern;" and (3) "in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems."

EPA initially proposed not to regulate perchlorate in 2008, but after reviewing public comments, the Agency published a final determination to regulate perchlorate under SDWA. 76 Fed. Reg. 7762 (February 11, 2011). This determination triggered a mandatory duty to propose an MCLG and NPDWR for perchlorate by February 11, 2013. SDWA § 1412(b)(1)(E). EPA has not yet proposed an MCLG and NPDWR for perchlorate, primarily due to the Agency's efforts to follow the recommendations of EPA's Science Advisory Board (SAB). When EPA, as required by SDWA §1412(e), asked the SAB for comments on the Agency's planned approach to deriving an MCLG for perchlorate, the Board recommended the Agency change course and develop a novel biologically based dose response ("BBDR") modeling approach instead. EPA has recently initiated the peer review process for the BBDR modeling approach it has developed for use in deriving an MCLG for perchlorate.

Consent Decree

The key terms of the draft consent decree are as follows:

- **October 18, 2017:** This is the date by which the decree states that EPA "intends" to complete peer review. If EPA determines that it will not complete the external peer review process by that date, EPA shall file a status report with the court no later than October 30, 2017, describing the progress of the external peer review process, the reason(s) for the delay, and an updated timeline for its completion.
- **October 31, 2018:** This is the date by which EPA shall sign for publication in the Federal Register a proposed MCLG and NPDWR for perchlorate.
- **December 19, 2019**: This is the date by which EPA shall sign for publication in the Federal Register a final MCLG and NPDWR for perchlorate.

Recommendation

We have recommended settlement of this matter, for several reasons. In this litigation, EPA has already conceded that it violated a mandatory duty to propose an MCLG and NPDWR for perchlorate. As the parties continue to disagree on whether the Agency also violated a mandatory duty to promulgate a final MCLG and

NPDWR, this settlement allows the Agency to Ex. 5 AC/AWP/DP

Ex. 5 AC/AWP/DP

Finally, the Office of Ground Water and Drinking Water (OGWDW) has evaluated the potential resources necessary to comply with the Consent Decree. OGWDW does not believe that Ex. 5 AC/AWP/DP

Ex. 5 AC/AWP/DP

We look forward to hearing from you. Again, if you have questions, you can reach me at 202-564-5517 or Carrie Wehling at 202-564-5492.

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 6/1/2020 2:49:39 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]

Subject: Perchlorate
Location: Skype Meeting

Start: 6/1/2020 5:00:00 PM
End: 6/1/2020 6:00:00 PM
Show Time As: Busy

-----Original Appointment-----
From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Thursday, May 28, 2020 5:36 PM
To: Burneson, Eric; Dorjets, Vlad EOP/OMB
Cc: Parikh, Pooja; Christ, Lisa
Subject: Perchlorate
When: Monday, June 01, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Skype Meeting

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Join Skype Meeting

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Find a local number

Conference ID: [Ex. 6 Personal Privacy (PP)]
Forgot your dial-in PIN? | Help

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From: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Sent: Thursday, May 28, 2020 12:26 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>
Subject: RE: Perchlorate

Let's go with 1:00 if that works for you and thanks for setting this up. And to be clear, this is just an informal chat to understand the thinking behind some of the decisions in the document. I don't plan to provide any comments at that time but simply ask a few questions to help inform my thinking as I prepare comments.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Thursday, May 28, 2020 12:22 PM
To: Dorjets, Vlad EOP/OMB < Ex. 6 Personal Privacy (PP)
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>
Subject: RE: Perchlorate

Vlad; I agree that it would be helpful to discuss the legal considerations involved in this action (including the timeline for clearing the action NLT June 17). I have checked with our General Counsel's Office representative and she is available at either 11am or 1 pm on Monday. Please let me know if you have a preference for either time and I can set up a meeting.
Eric

From: Dorjets, Vlad EOP/OMB < Ex. 6 Personal Privacy (PP)
Sent: Thursday, May 28, 2020 11:42 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Perchlorate

I imagine that a lot of what was drafted in the perchlorate rule is a result of very deliberate legal consideration. I think it would help me to understand whether Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) I expect to be done reading the document tomorrow (too many other things going on that prevent me from reading it straight through) so perhaps we could chat sometime on Monday?